

US3412126 (Prod: New Horizons Clinical Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:34:19

All time stamps listed in this document are displayed in GMT

US3412126

Form: Participant Creation

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

[Participant ID](#)

US3412126

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

US3412126

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 04:49:40

Generated On: 09 Jun 2021 17:34:19

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 04 AUG 2020

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

Folder OID SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 04:49:39

Generated On: 09 Jun 2021 17:34:19

Date of Birth (MMM yyyy)	(b) (6) 1959
Age	60
Age Units	YEARS
Age (Derived)	61
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
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

US3412126

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 04:49:39

Generated On: 09 Jun 2021 17:34:19

Date of Informed Consent (*dd MMM yyyy*) 04 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version Amendment 1
Amendment 2
Amendment 3
Amendment 4
Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail Withdrew Consent
Inclusion/Exclusion
Cohort Full
Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

US3412126

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 04:49:40

Generated On: 09 Jun 2021 17:34:19

Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 04:49:40

Generated On: 09 Jun 2021 17:34:19

Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 12 Apr 2021 14:35:04

Generated On: 09 Jun 2021 17:34:19

Condition	HYPERTENSION
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)	_____

US3412126

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Apr 2021 14:35:04

Generated On: 09 Jun 2021 17:34:19

Condition	OSTEOARTHRITIS HIPS AND SHOULDERS
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)	_____

US3412126

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Apr 2021 14:35:04

Generated On: 09 Jun 2021 17:34:19

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

US3412126

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Apr 2021 14:35:04

Generated On: 09 Jun 2021 17:34:19

Condition	POST MENOPAUSAL
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)	_____

US3412126

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 12 Apr 2021 14:35:04

Generated On: 09 Jun 2021 17:34:19

Condition	ALLERGIC RHINITIS - SEASONAL
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3412126

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 12 Apr 2021 14:35:04

Generated On: 09 Jun 2021 17:34:19

Condition	CHRONIC BRONCHITIS
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)	_____

US3412126

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 12 Apr 2021 14:35:04

Generated On: 09 Jun 2021 17:34:19

Condition	FROZEN SHOULDER - BILATERAL
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3412126

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 12 Apr 2021 14:35:04

Generated On: 09 Jun 2021 17:34:19

Condition	OSTEOPEROSIS
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)	

US3412126

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 12 Apr 2021 14:35:04

Generated On: 09 Jun 2021 17:34:19

Condition	SMOKING
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3412126

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 04:49:40

Generated On: 09 Jun 2021 17:34:19

Were vital signs assessed? Yes
No

Date of assessment (*dd MMM yyyy*) 04 AUG 2020

Time of assessment (*00:00-23:59*) 15:09 (24 HR)

Vital Signs Date and Time (derived) 04 AUG 2020 15:09

Height (*xxx.x*) 149.8 cm

Weight (*xxx.x*) 48.2 kg

BMI (*xxx.x*) 21.47946 kg/m²

BMI units KG/M2

Temperature (*xxx.x*) ND - Not Done

Route of measurement Oral
Axillary
Other

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) 13 Feb 2021 04:49:40

Generated On: 09 Jun 2021 17:34:19

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

04 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: Childbearing Potential

Data signed: (b) (4) 13 Feb 2021 04:49:39

Generated On: 09 Jun 2021 17:34:19

Date of assessment (*dd MMM yyyy*) 04 AUG 2020

Is the participant of childbearing potential? Yes
No

If No, what is the reason? Surgically sterile
Post-menopausal
Partner medically sterile
Not reached age of Menarche
Other

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (*dd MMM yyyy*) _____

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN UNK 2010

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 04:49:40

Generated On: 09 Jun 2021 17:34:19

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 (b) (6) FEMALE GOES TO GROCERY STORE, RESTAURANTS AND LIVES WITH ESSENTIAL WORKER

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 04:49:40

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Resides in Nursing Home or Assisted Living Facility	False
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)	True
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	True
Specify	LIVES IN HIGH RISK COUNTY

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:37:34

Generated On: 09 Jun 2021 17:34:19

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 04 AUG 2020

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

Folder OID VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 02:37:34

Generated On: 09 Jun 2021 17:34:19

What was the date of randomization? (dd MMM yyyy) 04 AUG 2020

What was the participant's randomization number? 100876

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

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

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

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

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

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

Liver Disease Yes No

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 02:37:34

Generated On: 09 Jun 2021 17:34:19

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:37:34

Generated On: 09 Jun 2021 17:34:19

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 (<i>dd MMM yyyy</i>)	04 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	15:09 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 15:09
Temperature (<i>xxx.x</i>)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	84 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	74 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:37:34

Generated On: 09 Jun 2021 17:34:19

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	04 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	16:53 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 16:53
Temperature (<i>xxx.x</i>)	98.1 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	66 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3412126

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:37:34

Generated On: 09 Jun 2021 17:34:19

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) 13 Feb 2021 02:37:34

Generated On: 09 Jun 2021 17:34:19

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) 04 AUG 2020

What was the treatment time? (00:00-23:59) 16:15 (24 HR)

Treatment Date and Time (derived) 04 AUG 2020 16:15

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

US3412126

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:37:34

Generated On: 09 Jun 2021 17:34:19

Was the sample collected? Yes
No

Collection date (*dd MMM yyyy*) 04 AUG 2020

Collection time (*00:00-23:59*) 15:40 (24 HR)

Collection date and time (derived) 04 AUG 2020 15:40

US3412126

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:37:34

Generated On: 09 Jun 2021 17:34:19

Collection date (<i>dd MMM yyyy</i>)			04 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:46	04 AUG 2020 15:46
Nasopharyngeal Swab 2	No		

US3412126

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:37:34

Generated On: 09 Jun 2021 17:34:19

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.1 °F

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

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

PC Time Stamp 04 AUG 2020 16:59

PC Open Date & Time 04 AUG 2020 16:35

PC Close Date & Time 04 AUG 2020 19:05

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:19

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

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 04 AUG 2020 20:00

PC Close Date & Time 05 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:19

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** 100.6 °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):

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

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

PC Time Stamp 05 AUG 2020 19:28

PC Open Date & Time 05 AUG 2020 12:00

PC Close Date & Time 06 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:19

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 99.8 °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):

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

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

PC Time Stamp 06 AUG 2020 19:33

PC Open Date & Time 06 AUG 2020 12:00

PC Close Date & Time 07 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:19

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** 100.4 °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):

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

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

PC Time Stamp 07 AUG 2020 19:35

PC Open Date & Time 07 AUG 2020 12:00

PC Close Date & Time 08 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:34:19

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 99.5 °F

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

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

PC Time Stamp 08 AUG 2020 19:13

PC Open Date & Time 08 AUG 2020 12:00

PC Close Date & Time 09 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:34:19

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	09 AUG 2020 19:26
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:34:19

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 99.2 °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):

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

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

PC Time Stamp 10 AUG 2020 19:17

PC Open Date & Time 10 AUG 2020 12:00

PC Close Date & Time 11 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

DAY 8

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	11 AUG 2020 19:39
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

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

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

Please record - **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

04 AUG 2020 17:01

PC Open Date & Time

04 AUG 2020 16:35

PC Close Date & Time

04 AUG 2020 19:05

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:19

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

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

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

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

- Yes
- No

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

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

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp

PC Open Date & Time

04 AUG 2020 20:00

PC Close Date & Time

05 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

DAY 2

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	05 AUG 2020 19:29
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

DAY 3

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	06 AUG 2020 19:33
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

DAY 4

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	07 AUG 2020 19:36
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

DAY 5

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

08 AUG 2020 19:14

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

DAY 6

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

09 AUG 2020 19:26

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

DAY 7

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

10 AUG 2020 19:18

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:19

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

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:19

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

No

Yes

PC Time stamp	04 AUG 2020 17:02
PC Open Date & Time	04 AUG 2020 16:35
PC Close Date & Time	04 AUG 2020 19:05

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:19

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

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:19

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

No

Yes

PC Time stamp

PC Open Date & Time

04 AUG 2020 20:00

PC Close Date & Time

05 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:19

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

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:19

	Yes <input type="checkbox"/>
PC Time stamp	05 AUG 2020 19:30
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:19

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

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:19

	Yes <input type="checkbox"/>
PC Time stamp	06 AUG 2020 19:34
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:19

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

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:19

	Yes <input type="checkbox"/>
PC Time stamp	07 AUG 2020 19:37
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:19

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

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:19

Yes

PC Time stamp	08 AUG 2020 19:14
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:19

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

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:19

	Yes <input type="checkbox"/>
PC Time stamp	09 AUG 2020 19:27
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:19

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

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:19

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

US3412126

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

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

PC Time Stamp 11 AUG 2020 19:39

PC Open Date & Time 11 AUG 2020 12:00

PC Close Date & Time 12 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

FATIGUE

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time Stamp

11 AUG 2020 19:39

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

FATIGUE

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time Stamp

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

FATIGUE

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time Stamp

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time stamp

11 AUG 2020 19:39

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time stamp

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **MUSCLE**

None

ACHES ALL OVER BODY

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time stamp

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**

None

ACHES IN SEVERAL JOINTS

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time stamp

11 AUG 2020 19:40

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None

No interference with activity

Some interference with activity not requiring medical attention

Prevents daily activity and requires medical attention

PC Open Date & Time 11 AUG 2020 12:00

PC Close Date & Time 12 AUG 2020 11:59

PC Time stamp 11 AUG 2020 19:40

US3412126

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	11 AUG 2020 19:40
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/> Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3412126

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3412126

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:49:39

Generated On: 09 Jun 2021 17:34:19

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 11 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3412126

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:49:39

Generated On: 09 Jun 2021 17:34:19

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412126

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:49:39

Generated On: 09 Jun 2021 17:34:19

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

US3412126

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:49:39

Generated On: 09 Jun 2021 17:34:19

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412126

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:55:44

Generated On: 09 Jun 2021 17:34:19

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3412126

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:49:39

Generated On: 09 Jun 2021 17:34:19

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412126

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:37:34

Generated On: 09 Jun 2021 17:34:19

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) _____

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

Folder OID VISIT2

US3412126

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:37:34

Generated On: 09 Jun 2021 17:34:19

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:37:34

Generated On: 09 Jun 2021 17:34:19

Timepoint Pre-Dose
Post-Dose

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 _____

US3412126

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:37:34

Generated On: 09 Jun 2021 17:34:19

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.

US3412126

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:37:34

Generated On: 09 Jun 2021 17:34:19

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? _____

What was the treatment date? (dd MMM yyyy) _____

What was the treatment time? (00:00-23:59) _____

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3412126

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:37:34

Generated On: 09 Jun 2021 17:34:19

Was the sample collected? Yes
No

Collection date (dd MMM yyyy) _____

Collection time (00:00-23:59) _____

Collection date and time (derived) _____

US3412126

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:37:34

Generated On: 09 Jun 2021 17:34:19

Collection date (*dd MMM yyyy*)

Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	No		
Nasopharyngeal Swab 2	No		

US3412126

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:22:28

Generated On: 09 Jun 2021 17:34:19

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412126

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:22:27

Generated On: 09 Jun 2021 17:34:19

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 SUBJECT WAS IN THE MIDDLE
If Contact Not Made, please provide Comments OF AN SAE AND DUE TO THE
ILLNESS SITE WAS TRYING TO
GET MEDICAL RECORDS
SUBJECTS SAE DID NOT
RESOLVE COMPLETELY UNTIL
20-JAN-2021

US3412126

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:22:27

Generated On: 09 Jun 2021 17:34:19

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412126

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:22:27

Generated On: 09 Jun 2021 17:34:19

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

SUBJECT WAS IN THE MIDDLE
OF AN SAE AND DUE TO THE
ILLNESS SITE WAS TRYING TO
GET MEDICAL RECORDS
SUBJECTS SAE DID NOT
RESOLVE COMPLETELY UNTIL
20-JAN-2021

US3412126

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:22:27

Generated On: 09 Jun 2021 17:34:19

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412126

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:22:27

Generated On: 09 Jun 2021 17:34:19

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

SUBJECT WAS IN THE MIDDLE
OF AN SAE AND DUE TO THE
ILLNESS SITE WAS TRYING TO
GET MEDICAL RECORDS
SUBJECTS SAE DID NOT
RESOLVE COMPLETELY UNTIL
20-JAN-2021

US3412126

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:22:27

Generated On: 09 Jun 2021 17:34:19

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412126

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:22:28

Generated On: 09 Jun 2021 17:34:19

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) _____

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

Folder OID VISIT3

US3412126

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:22:28

Generated On: 09 Jun 2021 17:34:19

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) _____

US3412126

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:22:28

Generated On: 09 Jun 2021 17:34:19

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.

US3412126

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:22:28

Generated On: 09 Jun 2021 17:34:19

Was the sample collected? Yes
No

Collection date (dd MMM yyyy) _____

Collection time (00:00-23:59) _____

Collection date and time (derived) _____

US3412126

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:22:28

Generated On: 09 Jun 2021 17:34:19

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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 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"/>

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

Patient Cloud Close Date & Time

08 OCT 2020 23:59

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

Patient Cloud Close Date & Time

15 OCT 2020 23:59

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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)	_____
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 <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"/>

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

01 NOV 2020 00:01

Patient Cloud Close Date & Time

05 NOV 2020 23:59

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)	_____
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 <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"/>

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

DAY 106

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

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

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

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

DAY 110

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

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

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2020 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

DAY 124

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

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

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 03 DEC 2020 00:01

[Patient Cloud Close Date & Time](#) 07 DEC 2020 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

DAY 138

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

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

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2020 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#) 28 DEC 2020 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

DAY 152

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

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

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

DAY 159

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

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

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

[Patient Cloud Close Date & Time](#)

11 JAN 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

DAY 166

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

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

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Date and time of submission	
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

[Patient Cloud Close Date & Time](#)

08 FEB 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

DAY 194

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

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

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

[Patient Cloud Close Date & Time](#)

15 FEB 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

DAY 201

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

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

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

[Patient Cloud Close Date & Time](#)

22 FEB 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

[Patient Cloud Close Date & Time](#)

08 MAR 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

[Patient Cloud Close Date & Time](#)

15 MAR 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

[Patient Cloud Close Date & Time](#)

22 MAR 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

DAY 236

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

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

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

[Patient Cloud Close Date & Time](#)

29 MAR 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

DAY 243

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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 <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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT DAY 278

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

10 MAY 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

DAY 285

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

13 MAY 2021 00:01

Patient Cloud Close Date & Time

17 MAY 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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°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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

24 MAY 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

31 MAY 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

03 JUN 2021 00:01

Patient Cloud Close Date & Time

07 JUN 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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°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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

14 JUN 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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°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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

21 JUN 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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="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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

28 JUN 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

01 JUL 2021 00:01

Patient Cloud Close Date & Time

05 JUL 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

08 JUL 2021 00:01

Patient Cloud Close Date & Time

12 JUL 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

DAY 348

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

15 JUL 2021 00:01

Patient Cloud Close Date & Time

19 JUL 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

26 JUL 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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°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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

02 AUG 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT	DAY 369
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

05 AUG 2021 00:01

Patient Cloud Close Date & Time

09 AUG 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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 <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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

12 AUG 2021 00:01

Patient Cloud Close Date & Time

16 AUG 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

23 AUG 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

30 AUG 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

06 SEP 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

13 SEP 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

16 SEP 2021 00:01

Patient Cloud Close Date & Time

20 SEP 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

27 SEP 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

30 SEP 2021 00:01

Patient Cloud Close Date & Time

04 OCT 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

11 OCT 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

14 OCT 2021 00:01

Patient Cloud Close Date & Time

18 OCT 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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°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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

21 OCT 2021 00:01

Patient Cloud Close Date & Time

25 OCT 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

01 NOV 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

08 NOV 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

15 NOV 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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°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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2021 00:01

Patient Cloud Close Date & Time

22 NOV 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

29 NOV 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

06 DEC 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

13 DEC 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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 <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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

16 DEC 2021 00:01

Patient Cloud Close Date & Time

20 DEC 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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 <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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

27 DEC 2021 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT DAY 516

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

30 DEC 2021 00:01

Patient Cloud Close Date & Time

03 JAN 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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 <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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

10 JAN 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

DAY 530

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

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

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

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

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

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

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

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

13 JAN 2022 00:01

Patient Cloud Close Date & Time

17 JAN 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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°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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

24 JAN 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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°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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

31 JAN 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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 <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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

03 FEB 2022 00:01

Patient Cloud Close Date & Time

07 FEB 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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°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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

14 FEB 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

21 FEB 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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 <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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

28 FEB 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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°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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

03 MAR 2022 00:01

Patient Cloud Close Date & Time

07 MAR 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

14 MAR 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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°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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

21 MAR 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

28 MAR 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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
Yes

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

04 APR 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

11 APR 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

14 APR 2022 00:01

Patient Cloud Close Date & Time

18 APR 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

21 APR 2022 00:01

Patient Cloud Close Date & Time

25 APR 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

02 MAY 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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°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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

05 MAY 2022 00:01

Patient Cloud Close Date & Time

09 MAY 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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°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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

12 MAY 2022 00:01

Patient Cloud Close Date & Time

16 MAY 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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°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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

23 MAY 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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°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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

30 MAY 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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
Yes

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

06 JUN 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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 <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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

13 JUN 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

16 JUN 2022 00:01

Patient Cloud Close Date & Time

20 JUN 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

27 JUN 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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°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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

30 JUN 2022 00:01

Patient Cloud Close Date & Time

04 JUL 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

11 JUL 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

14 JUL 2022 00:01

Patient Cloud Close Date & Time

18 JUL 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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°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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

21 JUL 2022 00:01

Patient Cloud Close Date & Time

25 JUL 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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°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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

01 AUG 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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°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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

08 AUG 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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
Yes

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

15 AUG 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

DAY 747

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

22 AUG 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

29 AUG 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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 <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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

01 SEP 2022 00:01

Patient Cloud Close Date & Time

05 SEP 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT DAY 768

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

08 SEP 2022 00:01

Patient Cloud Close Date & Time

12 SEP 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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°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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

15 SEP 2022 00:01

Patient Cloud Close Date & Time

19 SEP 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

26 SEP 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

03 OCT 2022 23:59

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

Patient Cloud Close Date & Time

10 OCT 2022 23:59

US3412126

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:34:19

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
---	--	---------------------------

US3412126

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:22:27

Generated On: 09 Jun 2021 17:34:19

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 SUBJECT WAS IN THE MIDDLE
OF AN SAE AND DUE TO THE
ILLNESS SITE WAS TRYING TO
GET MEDICAL RECORDS
SUBJECTS SAE DID NOT
RESOLVE COMPLETELY UNTIL
20-JAN-2021

If Contact Not Made, please provide Comments

US3412126

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:22:27

Generated On: 09 Jun 2021 17:34:19

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412126

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:22:27

Generated On: 09 Jun 2021 17:34:19

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 SUBJECT WAS IN THE MIDDLE
OF AN SAE AND DUE TO THE
ILLNESS SITE WAS TRYING TO
GET MEDICAL RECORDS
SUBJECTS SAE DID NOT
RESOLVE COMPLETELY UNTIL
20-JAN-2021

If Contact Not Made, please provide Comments

US3412126

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:22:27

Generated On: 09 Jun 2021 17:34:19

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412126

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:22:27

Generated On: 09 Jun 2021 17:34:19

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 SUBJECT WAS IN THE MIDDLE
OF AN SAE AND DUE TO THE
ILLNESS SITE WAS TRYING TO
GET MEDICAL RECORDS
SUBJECTS SAE DID NOT
RESOLVE COMPLETELY UNTIL
20-JAN-2021

If Contact Not Made, please provide Comments

US3412126

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:22:27

Generated On: 09 Jun 2021 17:34:19

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412126

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:22:27

Generated On: 09 Jun 2021 17:34:19

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 SUBJECT WAS IN THE MIDDLE
OF AN SAE AND DUE TO THE
ILLNESS SITE WAS TRYING TO
GET MEDICAL RECORDS
SUBJECTS SAE DID NOT
RESOLVE COMPLETELY UNTIL
20-JAN-2021

If Contact Not Made, please provide Comments

US3412126

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:22:27

Generated On: 09 Jun 2021 17:34:19

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412126

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:22:28

Generated On: 09 Jun 2021 17:34:19

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) _____

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

Folder OID VISIT4

US3412126

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:22:28

Generated On: 09 Jun 2021 17:34:19

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) _____

US3412126

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:22:28

Generated On: 09 Jun 2021 17:34:19

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.

US3412126

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:22:28

Generated On: 09 Jun 2021 17:34:19

Was the sample collected? Yes
No

Collection date (dd MMM yyyy) _____

Collection time (00:00-23:59) _____

Collection date and time (derived) _____

US3412126

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:22:28

Generated On: 09 Jun 2021 17:34:19

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412126

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:19

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 _____

US3412126

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:19

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: COVID-19 Contact

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

Date of Contact 12 AUG 2020

Time of Contact 16:45

Date and Time of Contact (derived) 12 AUG 2020 16:45

Type of Contact

Clinic Visit - Scheduled

Clinical Visit - Unscheduled

Safety Call

Convalescent Tele-visit

Has the subject reported symptoms of SARS-COV-2?

Yes

No

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

Symptom Day

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

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

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

Date	12 AUG 2020
------	-------------

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

O2 Saturation	ND - Not Done
---------------	---------------

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

Temperature	99.2 F
-------------	--------

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

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

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

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

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EAB) (1725)

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US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

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

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

Symptom Day

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

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Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

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

Date	13 AUG 2020
------	-------------

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

O2 Saturation	99 %
---------------	------

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

Temperature	97.5 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

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Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

Symptom Day

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

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Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

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

Date	14 AUG 2020
------	-------------

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

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

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

Temperature	98.2 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

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

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Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

Symptom Day

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

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Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

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

Date	15 AUG 2020
------	-------------

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

O2 Saturation	98 %
---------------	------

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

Temperature	98 F
-------------	------

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

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

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

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

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Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

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

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Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

Symptom Day

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

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Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

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

Date	16 AUG 2020
------	-------------

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

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

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

Temperature	98.1 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

Symptom Day

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

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Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

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

Date	17 AUG 2020
------	-------------

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

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

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

Temperature	98.2 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

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

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Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

Symptom Day

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

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Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

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

Date	18 AUG 2020
------	-------------

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

O2 Saturation	96 %
---------------	------

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

Temperature	98.2 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

Not Done

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

Symptom Day

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

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

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

Date 05 AUG 2020

Assessment Not Done True

O2 Saturation _____

O2 Saturation Units _____

Temperature _____

Chills

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

Cough

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

Shortness of Breath

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

Difficulty Breathing

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

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

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

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

Symptom Day

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

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

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

Date	06 AUG 2020
------	-------------

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

O2 Saturation	<hr/>
---------------	-------

O2 Saturation Units	<hr/>
---------------------	-------

Temperature	<hr/>
-------------	-------

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

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

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

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

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

Not Done

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

Symptom Day

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

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

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

Date 07 AUG 2020

Assessment Not Done True

O2 Saturation _____

O2 Saturation Units _____

Temperature _____

Chills

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

Cough

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

Shortness of Breath

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

Difficulty Breathing

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

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

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

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

Symptom Day

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

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

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

Date	08 AUG 2020
------	-------------

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

O2 Saturation	<hr/>
---------------	-------

O2 Saturation Units	<hr/>
---------------------	-------

Temperature	<hr/>
-------------	-------

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

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

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

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

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

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

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

Symptom Day

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

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

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

Date 09 AUG 2020

Assessment Not Done True

O2 Saturation _____

O2 Saturation Units _____

Temperature _____

Chills

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

Cough

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

Shortness of Breath

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

Difficulty Breathing

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

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

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

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

Symptom Day

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

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

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

Date	10 AUG 2020
------	-------------

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

O2 Saturation	<hr/>
---------------	-------

O2 Saturation Units	<hr/>
---------------------	-------

Temperature	<hr/>
-------------	-------

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

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

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

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

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

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

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

Symptom Day

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

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

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

Date 11 AUG 2020

Assessment Not Done True

O2 Saturation _____

O2 Saturation Units _____

Temperature _____

Chills

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

Cough

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

Shortness of Breath

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

Difficulty Breathing

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

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

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

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

Date of Visit 12 AUG 2020

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

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

Date of Test 12 AUG 2020

Type of Test Performed Nasopharyngeal Swab
Nasal Swab
Saliva Test
Other

Other, specify _____

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

If yes, provide lab information below

Lab/ Institution Test Performed _____

CLIA Certified? Yes
No

COVID-19 Positive (CSA Programming Field Only) 0

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:34:19

[Generate Next COVID-19 Assessment](#)

Yes

No

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 16 Apr 2021 14:22:26

Generated On: 09 Jun 2021 17:34:19

Visit	Was Saliva Collected?	Date of Collection
Day 3	No	
Day 5	No	
Day 7	No	
Day 9	No	
Day 14	No	
Day 21	No	
Day 28	No	

US3412126

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:22:26

Generated On: 09 Jun 2021 17:34:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3412126

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:22:26

Generated On: 09 Jun 2021 17:34:19

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	12 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	16:51 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 16:51
Height (<i>xxx.x</i>)	151 cm
Weight (<i>xxx.x</i>)	42 kg
Temperature (<i>xxx.x</i>)	99.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	90 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3412126

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:22:26

Generated On: 09 Jun 2021 17:34:19

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

12 AUG 2020

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

US3412126

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 16 Apr 2021 14:22:26

Generated On: 09 Jun 2021 17:34:19

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
	NA (COVID-19 Negative) <input type="radio"/>

Date of Collection	12 AUG 2020
--------------------	-------------

US3412126

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

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:22:26

Generated On: 09 Jun 2021 17:34:19

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 24 FEB 2021

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

Folder OID UNBLND_DECIDE

US3412126

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 14:22:26

Generated On: 09 Jun 2021 17:34:19

Date of updated informed consent (*dd MMM yyyy*) 24 FEB 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*) 24 FEB 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 _____

US3412126

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:22:26

Generated On: 09 Jun 2021 17:34:19

Was the sample collected?

Yes

No

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3412126

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Apr 2021 14:22:26

Generated On: 09 Jun 2021 17:34:19

Was the sample collected?

Yes

No

Collection date (dd MMM yyyy)

Collection time (00:00 - 23:59)

Collection Date and Time (derived)

US3412126

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Mar 2021 15:31:04

Generated On: 09 Jun 2021 17:34:19

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 14:40:59

Generated On: 09 Jun 2021 17:34:19

AEID

Adverse event

UPPER RESPIRATORY
INFECTION

Was this a medically-attended AE?

Yes

No

Was this a Solicited Adverse Reaction?

Yes

No

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

Yes

No

Start date (dd MMM yyyy)

05 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes

No

If not Ongoing, end date (dd MMM yyyy)

18 AUG 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild

Grade 2/Moderate

Grade 3/Severe

Grade 4

Is the adverse event serious?

Yes

No

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes

No

Unknown

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 14:40:59

Generated On: 09 Jun 2021 17:34:19

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

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 14:40:59

Generated On: 09 Jun 2021 17:34:19

AEID	
Adverse event	RIB PAIN
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)	23 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	22 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 14:40:59

Generated On: 09 Jun 2021 17:34:19

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

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 14:40:59

Generated On: 09 Jun 2021 17:34:19

AEID USA-US061-2020-MRNA-1273-P30
1000004

Adverse event ABSCESS OF LUNG

Was this a medically-attended AE? Yes
No

Was this a Solicited Adverse Reaction? Yes
No

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes
No

Start date (dd MMM yyyy) 22 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 20 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild
Grade 2/Moderate
Grade 3/Severe
Grade 4

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 22 AUG 2020

Hospital Discharge Date (dd MMM yyyy) 01 SEP 2020

Admitted to ICU? Yes
No
Unknown

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 14:40:59

Generated On: 09 Jun 2021 17:34:19

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
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

Action taken with investigational product None
Dose Delayed
Investigational Product
Withdrawn
Not Applicable

Other action taken (check all that apply)

None False

Concomitant Medication True

Concomitant Procedure False

Outcome Fatal
Not Recovered/Not Resolved
Recovered/Resolved
Recovered/Resolved with
Sequelae
Recovering/Resolving
Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 14:40:59

Generated On: 09 Jun 2021 17:34:19

(b) (6) FEMALE
WITH CHEST PAIN. PT HAS
SEVERE, SHARP PAIN, WORSE
WITH COUGHING. PAIN
LOCATED ON RIGHT SIDE. PT
HAD PAIN STARTING THE
FOLLOWING DAY. FELT LIKE
SHE HAD A BROKEN RIB. SHE IS
A SMOKER. ASSOCIATED
SYMPTOMS INCLUDE POOR
APPETITE, DYSPNEA. PATIENT
WAS FOUND TO HAVE
CAVITARY PNA. NOW S/P
BRONCH. ID ON BOARD FOR
ABX MANAGMENT. PLAN FOR
LONG TERM IV ABX AT HOME (
ZOSYN) FOR AN ADDITIONAL 3
WEEKS. CRX WITH STABLE
EXTENSIVE R MIDDLE LOBE
INFILTRATE/ CONSOLIDATION
WITH KNOWN
INTRAPARENCHYMAL
ABCESS.

INITIAL LABS SHOWED
LEUCOCYTOSIS, BLOOD CX SO
FAR NGTD. CT SHOWED
MULTIFOCAL CONSOLIDATION
AND FLUID IN THE RML
CONCERNING FOR ABCESS.
SEEN BY PULMONOLOGY,
UNDERWENT BRONCHOSCOPY
WITH BAL ON 8/25/20. BAL
CULTURES AND CYTOLOGY
PENDING ID WAS

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 14:40:59

Generated On: 09 Jun 2021 17:34:19

CONSULTED FOR ANTIBIOTIC
MANAGEMENT.

CULTURE RESULTS
STAPHYLOCOCCUS AUREUS
WAS NOT DETECTED
STREP PNEUMO ANTIGEN WAS
NOT DETECTED
LEGIONELLA ANTIGEN URINE
WAS NOT DETCTED
LOWER REPIRATORY CULTURE
NO WBC'S SEEN AND NO
ORGANISMS SEEN.

RESP VIRUS
RSP FAC SOURCE = BAL
INFLUENZA A-DFA NEGATIVE
INFLUENZA B-DFA NEGATIVE
PARAINFLUENZA 1- DFA
NEGATIVE
PARAINFLUENZA 2-DFA
NEGATIVE
PARAINFLUENZA 3- DFA
NEGATIVE
ADENOVIRUS- DFA NEGATIVE
RSV-DFA NEGATIVE
HUMAN METAPNEUMOVIRUS -
DFA NEGATIVE
FUNGUS CULTURE POSITIVE
GROWTH SPARSE GROWTH OF
YEAST, SUSPECT CANDIDA
SPECIES, POSSIBLE
REPARATORY TRACT COLON
OVERVIEW: SUBJECT WAS
ADMITTED

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 14:40:59

Generated On: 09 Jun 2021 17:34:19

FROM 8/23/20 - 9/01/2020 IN WHICH SHE PRESENTED FOR EVALUATION OF A DRY COUGH AND CHEST/RIB PAIN. THE SYMPTOMS WERE DESCRIBED AS ONGOING AND PROGRESSIVELY WORSENING, CHEST IMAGING WAS OBTAINED AND REVEALED MULTIFOCAL CONSOLIDATION AND FLUID IN THE RIGHT MIDDLE LOBE CONCERNING FOR AN ABSCESS, INFECTIOUS DISEASE WAS CONSULTED FOR ANTIBIOTIC MANAGEMENT. SHE WAS MEDICALLY CLEARED FOR DISCHARGE ON 9/1/20 AND RECEIVED IV ZOSYN UNTIL 9/22/20. AS OF 9/10/20 SUBJECT DID NOT REPORT ANY FEVER, CHILLS, NAUSEA, VOMITING, OR DIARRHEA. SUBJECT HAS FOLLOW UPS THAT HAVE CAME BACK WITHOUT CONCERN

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

US3412126

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Apr 2021 14:40:59

Generated On: 09 Jun 2021 17:34:19

AEID USA-US061-2020-MRNA-1273-P30
1000004

Adverse event PNEUMONIA

Was this a medically-attended AE? Yes
No

Was this a Solicited Adverse Reaction? Yes
No

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes
No

Start date (dd MMM yyyy) 22 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 20 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild
Grade 2/Moderate
Grade 3/Severe
Grade 4

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 22 AUG 2020

Hospital Discharge Date (dd MMM yyyy) 01 SEP 2020

Admitted to ICU? Yes
No
Unknown

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Apr 2021 14:40:59

Generated On: 09 Jun 2021 17:34:19

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
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

Action taken with investigational product None
Dose Delayed
Investigational Product
Withdrawn
Not Applicable

Other action taken (check all that apply)

None False

Concomitant Medication True

Concomitant Procedure True

Outcome Fatal
Not Recovered/Not Resolved
Recovered/Resolved
Recovered/Resolved with
Sequelae
Recovering/Resolving
Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative

US3412126

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Apr 2021 14:40:59

Generated On: 09 Jun 2021 17:34:19

(b) (6) FEMALE
WITH CHEST PAIN. PT HAS
SEVERE, SHARP PAIN, WORSE
WITH COUGHING. PAIN
LOCATED ON RIGHT SIDE. PT
HAD PAIN STARTING THE
FOLLOWING DAY. FELT LIKE
SHE HAD A BROKEN RIB. SHE IS
A SMOKER. ASSOCIATED
SYMPTOMS INCLUDE POOR
APPETITE, DYSPNEA. PATIENT
WAS FOUND TO HAVE
CAVITARY PNA. NOW S/P
BRONCH. ID ON BOARD FOR
ABX MANAGMENT. PLAN FOR
LONG TERM IV ABX AT HOME (
ZOSYN) FOR AN ADDITIONAL 3
WEEKS. CRX WITH STABLE
EXTENSIVE R MIDDLE LOBE
INFILTRATE/ CONSOLIDATION
WITH KNOWN
INTRAPARENCHYMAL
ABSCESS.

INITIAL LABS SHOWED
LEUCOCYTOSIS, BLOOD CX SO
FAR NGTD. CT SHOWED
MULTIFOCAL CONSOLIDATION
AND FLUID IN THE RML
CONCERNING FOR ABSCESS.
SEEN BY PULMONOLOGY,
UNDERWENT BRONCHOSCOPY
WITH BAL ON 8/25/20. BAL
CULTURES AND CYTOLOGY
PENDING ID WAS

US3412126

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Apr 2021 14:40:59

Generated On: 09 Jun 2021 17:34:19

CONSULTED FOR ANTIBIOTIC
MANAGEMENT.

CULTURE RESULTS
STAPHYLOCOCCUS AUREUS
WAS NOT DETECTED
STREP PNEUMO ANTIGEN WAS
NOT DETECTED
LEGIONELLA ANTIGEN URINE
WAS NOT DETCTED
LOWER REPIRATORY CULTURE
NO WBC'S SEEN AND NO
ORGANISMS SEEN.

RESP VIRUS
RSP FAC SOURCE = BAL
INFLUENZA A-DFA NEGATIVE
INFLUENZA B-DFA NEGATIVE
PARAINFLUENZA 1- DFA
NEGATIVE
PARAINFLUENZA 2-DFA
NEGATIVE
PARAINFLUENZA 3- DFA
NEGATIVE
ADENOVIRUS- DFA NEGATIVE
RSV-DFA NEGATIVE
HUMAN METAPNEUMOVIRUS -
DFA NEGATIVE
FUNGUS CULTURE POSITIVE
GROWTH SPARSE GROWTH OF
YEAST, SUSPECT CANDIDA
SPECIES, POSSIBLE
REPARATORY TRACT COLON
OVERVIEW: SUBJECT WAS
ADMITTED

US3412126

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Apr 2021 14:40:59

Generated On: 09 Jun 2021 17:34:19

FROM 8/23/20 - 9/01/2020 IN WHICH SHE PRESENTED FOR EVALUATION OF A DRY COUGH AND CHEST/RIB PAIN. THE SYMPTOMS WERE DESCRIBED AS ONGOING AND PROGRESSIVELY WORSENING, CHEST IMAGING WAS OBTAINED AND REVEALED MULTIFOCAL CONSOLIDATION AND FLUID IN THE RIGHT MIDDLE LOBE CONCERNING FOR AN ABSCESS, INFECTIOUS DISEASE WAS CONSULTED FOR ANTIBIOTIC MANAGEMENT. SHE WAS MEDICALLY CLEARED FOR DISCHARGE ON 9/1/20 AND RECEIVED IV ZOSYN UNTIL 9/22/20. AS OF 9/10/20 SUBJECT DID NOT REPORT ANY FEVER, CHILLS, NAUSEA, VOMITING, OR DIARRHEA. SUBJECT HAS FOLLOW UPS THAT HAVE CAME BACK WITHOUT CONCERN

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

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Apr 2021 14:35:04

Generated On: 09 Jun 2021 17:34:19

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

Yes

No

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

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

Name of Medication OXYCODONE-ACETAMINOPHE
N

Prophylaxis Yes
No

Indication OSTEOARTHRITIS

Dose per administration 5/325

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2015

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

Name of Medication CARTIA

Prophylaxis Yes
No

Indication HYPERTENSION

Dose per administration 300

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2015

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 01 SEP 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

Name of Medication CELEXA

Prophylaxis Yes
No

Indication ANXIETY

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2015

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

Name of Medication DICLOFENAC

Prophylaxis Yes
No

Indication OSTEOARTHRITIS

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
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2015

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

Name of Medication FUROSEMIDE

Prophylaxis Yes
No

Indication HYPERTENSION

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2015

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

Name of Medication POTASSIUM CHLORIDE

Prophylaxis Yes
No

Indication GENERAL HEALTH

Dose per administration 10

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify MEQ

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2016

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

Name of Medication TIZANIDINE HYDROCHLORIDE

Prophylaxis Yes
No

Indication OSTEOARTHRITIS

Dose per administration 4

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2010

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 3

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

Name of Medication CALCIUM CHLORIDE - 10%

Prophylaxis Yes
No

Indication OSTEOPOROSIS

Dose per administration 500

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2014

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

Name of Medication PROLIA

Prophylaxis Yes
No

Indication OSTEOPOROSIS

Dose per administration 60

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

TWO TIMES PER YEAR

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2018

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

Name of Medication ASPIRIN

Prophylaxis Yes
No

Indication URI

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
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 05 AUG 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 18 AUG 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

Name of Medication GUAIFENESIN

Prophylaxis Yes
No

Indication ALLERGIC RHINITIS - SEASONAL

Dose per administration 100/5

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify MG/ML

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2017

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 3

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

Name of Medication PIPERACILLIN-TAZOBACTAM

Prophylaxis Yes
No

Indication AE - PNEUMONIA

Dose per administration 3.375

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

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*) 26 AUG 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 22 SEP 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 3

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

Name of Medication BENZONATATE

Prophylaxis Yes
No

Indication URI - UPPER RESPIRATORY INFECTION

Dose per administration 200

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

	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)	14 AUG 2020
--------------------------	-------------

Start date completely unknown	False
-------------------------------	-------

Ongoing?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>

If not Ongoing, End date (dd MMM yyyy)	18 AUG 2020
--	-------------

Was this medication taken for solicited event?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>

Separate Dosage Number (derived)	3
----------------------------------	---

Interval Dosage Unit Number (derived)	1
---------------------------------------	---

Interval Dosage Definition (derived)	802 <input type="checkbox"/>
	803 <input type="checkbox"/>
	804 <input checked="" type="checkbox"/>

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

Name of Medication ASPIRIN

Prophylaxis Yes
No

Indication FEVER FOR URI

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
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

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*) 08 AUG 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 18 AUG 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

Name of Medication NASACORT - 55MCG

Prophylaxis Yes
No

Indication SEASONAL ALLERGIES

Dose per administration 55

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

Intramuscular	<input type="radio"/>
Respiratory (Inhalation)	<input type="radio"/>
Intralesional	<input type="radio"/>
Intraperitoneal	<input type="radio"/>
Nasal	<input checked="" 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*) 08 OCT 2019

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

Name of Medication MOMETASONE - 50MCG

Prophylaxis Yes
No

Indication SEASONAL ALLERGIES

Dose per administration 50

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input checked="" type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 20 AUG 2019

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

Name of Medication MORPHINE

Prophylaxis Yes
No

Indication RIB PAIN

Dose per administration 8

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

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*) 24 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 24 OCT 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

Name of Medication AZITHROMYCIN

Prophylaxis Yes
No

Indication PNEUMONIA

Dose per administration 500

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

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*) 23 AUG 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 24 AUG 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

Name of Medication ROCEPHIN

Prophylaxis Yes
No

Indication PNEUMONIA

Dose per administration 2

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

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*) 23 AUG 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 23 AUG 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

Name of Medication LOVENOX

Prophylaxis Yes
No

Indication DVT PROPHYLAXIS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

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) 23 AUG 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 01 SEP 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

Name of Medication ZOFRAN

Prophylaxis Yes
No

Indication NAUSEA PROPHYLACTIC

Dose per administration 4

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal
- Rectal
- Intravenous
- Intravenous Bolus
- Intravenous Drip
- Other

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 23 AUG 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 01 SEP 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

Name of Medication MORPHINE

Prophylaxis Yes
No

Indication RIB PAIN / PNEUMONIA

Dose per administration 8

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

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*) 23 AUG 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 01 SEP 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

Name of Medication SOLUMEDROL

Prophylaxis Yes
No

Indication PNEUMONIA

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 16 Apr 2021 13:30:24

Generated On: 09 Jun 2021 17:34:19

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*) 23 AUG 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 01 SEP 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Apr 2021 14:35:04

Generated On: 09 Jun 2021 17:34:19

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 12 Apr 2021 14:35:04

Generated On: 09 Jun 2021 17:34:19

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
25 AUG 2020	BRONCHOSCOPY WITH BAL DONE ON 25-AUG-2020)	Adverse Event	
23 AUG 2020	X-RAY CHEST (PA&LATERAL)	Adverse Event	
22 AUG 2020	CT PULMONARY ANGIOGRAM	Adverse Event	
31 AUG 2020	XRAY CHEST (PA&LATERAL)	Adverse Event	
31 AUG 2020	PICC LINE INSERTION	Adverse Event	
23 AUG 2020	ECG'S DAILY FROM 23-AUG-2020 TO 30-AUG-2020	Adverse Event	
23 AUG 2020	INITIAL LABS SHOWED LEUCOCYTOSIS, BLOOD CX SO FARD NGTD	Adverse Event	
23 AUG 2020	BAL CULTURES AND CYTOLOGY	Adverse Event	
19 OCT 2020	CHEST CT	Adverse Event	
20 JAN 2021	CHEST CT	Adverse Event	

US3412126

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 16 Apr 2021 14:22:26

Generated On: 09 Jun 2021 17:34:19

Date of dosing discontinuation (dd MMM yyyy) 21 SEP 2020

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 AE#3

US3412126

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 16 Apr 2021 14:22:26

Generated On: 09 Jun 2021 17:34:19

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

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 14:40:59

Generated On: 09 Jun 2021 17:34:19

SAEID	USA-US061-2020-MRNA-1273-P301000004
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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 14:40:59

Generated On: 09 Jun 2021 17:34:19

SAEID	USA-US061-2020-MRNA-1273-P301000004
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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	18
Date of submission (Pre-filled from custom function)	28/AUG/2020 13:09
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

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 14:40:59

Generated On: 09 Jun 2021 17:34:19

SAEID	USA-US061-2020-MRNA-1273-P301000004
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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	18
Date of submission (Pre-filled from custom function)	20/SEP/2020 16:22
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.	<input checked="" type="checkbox"/> True

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 14:40:59

Generated On: 09 Jun 2021 17:34:19

SAEID	USA-US061-2020-MRNA-1273-P301000004
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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	18
Date of submission (Pre-filled from custom function)	22/SEP/2020 09:11
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

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Apr 2021 14:40:59

Generated On: 09 Jun 2021 17:34:19

SAEID	USA-US061-2020-MRNA-1273-P301000004
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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	18
Date of submission (Pre-filled from custom function)	02/OCT/2020 08:55
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Data signed: (b) (4) 26 Apr 2021 14:40:59

Generated On: 09 Jun 2021 17:34:19

SAEID USA-US061-2020-MRNA-1273-P30
1000004

Serious Yes
No

Death Yes
No

Life threatening Yes
No

Requires inpatient or prolongation of existing Hospitalization Yes
No

Persistent or significant disability or incapacity Yes
No

Congenital anomaly or birth defect Yes
No

Other medically important event Yes
No

Investigator's First Name RICHARD

Investigator's Last Name POWELL

Site Address: Street _____

Site Address: City _____

Site Address: State OH

Site Address: Postal Code _____

Investigator Country US

E2B Transmit Flag (Derived/Hidden) 18

Date of submission (Pre-filled from custom function) 22/OCT/2020 16:53

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. True

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Data signed: (b) (4) 26 Apr 2021 14:40:59

Generated On: 09 Jun 2021 17:34:19

SAEID	USA-US061-2020-MRNA-1273-P301000004
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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	18
Date of submission (Pre-filled from custom function)	27/OCT/2020 13:19
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.	<input checked="" type="checkbox"/> True

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

Data signed: (b) (4) 26 Apr 2021 14:40:59

Generated On: 09 Jun 2021 17:34:19

SAEID	USA-US061-2020-MRNA-1273-P301000004
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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	18
Date of submission (Pre-filled from custom function)	28/OCT/2020 09:06
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.	<input checked="" type="checkbox"/> True

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (8)

Data signed: (b) (4) 26 Apr 2021 14:40:59

Generated On: 09 Jun 2021 17:34:19

SAEID	USA-US061-2020-MRNA-1273-P301000004
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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	18
Date of submission (Pre-filled from custom function)	12/NOV/2020 01:29
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.	<input checked="" type="checkbox"/> True

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (9)

Data signed: (b) (4) 26 Apr 2021 14:40:59

Generated On: 09 Jun 2021 17:34:19

SAEID	USA-US061-2020-MRNA-1273-P301000004
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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	18
Date of submission (Pre-filled from custom function)	23/NOV/2020 21:33
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

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (10)

Data signed: (b) (4) 26 Apr 2021 14:40:59

Generated On: 09 Jun 2021 17:34:19

SAEID	USA-US061-2020-MRNA-1273-P301000004
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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	18
Date of submission (Pre-filled from custom function)	25/NOV/2020 14:02
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.	<input checked="" type="checkbox"/> True

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (11)

Data signed: (b) (4) 26 Apr 2021 14:40:59

Generated On: 09 Jun 2021 17:34:19

SAEID	USA-US061-2020-MRNA-1273-P301000004
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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	18
Date of submission (Pre-filled from custom function)	14/DEC/2020 15:53
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	<input checked="" type="checkbox"/> True

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (12)

Data signed: (b) (4) 26 Apr 2021 14:40:59

Generated On: 09 Jun 2021 17:34:19

SAEID	USA-US061-2020-MRNA-1273-P301000004
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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	18
Date of submission (Pre-filled from custom function)	
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.	False

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (13)

Data signed: (b) (4) 26 Apr 2021 14:40:59

Generated On: 09 Jun 2021 17:34:19

SAEID	USA-US061-2020-MRNA-1273-P301000004
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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	18
Date of submission (Pre-filled from custom function)	18/DEC/2020 15:29
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.	<input checked="" type="checkbox"/> True

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (14)

Data signed: (b) (4) 26 Apr 2021 14:40:59

Generated On: 09 Jun 2021 17:34:19

SAEID	USA-US061-2020-MRNA-1273-P301000004
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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	18
Date of submission (Pre-filled from custom function)	18/FEB/2021 17:10
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.	<input checked="" type="checkbox"/> True

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (15)

Data signed: (b) (4) 26 Apr 2021 14:40:59

Generated On: 09 Jun 2021 17:34:19

SAEID	USA-US061-2020-MRNA-1273-P301000004
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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	18
Date of submission (Pre-filled from custom function)	19/FEB/2021 12:28
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.	<input checked="" type="checkbox"/> True

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (16)

Data signed: (b) (4) 26 Apr 2021 14:40:59

Generated On: 09 Jun 2021 17:34:19

SAEID	USA-US061-2020-MRNA-1273-P301000004
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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	18
Date of submission (Pre-filled from custom function)	16/MAR/2021 08:21
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.	<input checked="" type="checkbox"/> True

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (17)

Data signed: (b) (4) 26 Apr 2021 14:40:59

Generated On: 09 Jun 2021 17:34:19

SAEID	USA-US061-2020-MRNA-1273-P301000004
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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	18
Date of submission (Pre-filled from custom function)	07/APR/2021 14:01
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.	<input checked="" type="checkbox"/> True

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (18)

Data signed: (b) (4) 26 Apr 2021 14:40:59

Generated On: 09 Jun 2021 17:34:19

SAEID	USA-US061-2020-MRNA-1273-P301000004
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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	18
Date of submission (Pre-filled from custom function)	19/APR/2021 14:36
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.	<input checked="" type="checkbox"/> True

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (19)

Data signed: (b) (4) 26 Apr 2021 14:40:59

Generated On: 09 Jun 2021 17:34:19

SAEID	USA-US061-2020-MRNA-1273-P301000004
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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	18
Date of submission (Pre-filled from custom function)	22/APR/2021 06:36
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.	<input checked="" type="checkbox"/> True

Audit

US3412126 (Prod: New Horizons Clinical Research)

US3412126

Form: Participant Creation

Generated On: 09 Jun 2021 17:34:19

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered 'US3412126'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 19:19:42

US3412126

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:34:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:36
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:09:11

US3412126

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:36
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '04 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 19:19:43

US3412126

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:34:19

[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 22:54:36
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:09:11

US3412126

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:34:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:36
User entered 'SCRN'	System	04 Aug 2020 20:09:11

US3412126

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:19

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered (b) (6) 1959'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 19:19:44

US3412126

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:19

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '60'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:09:22

US3412126

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:19

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered 'YEARS'	System	04 Aug 2020 20:09:22

US3412126

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:19

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered '61'	System	04 Aug 2020 20:09:34

US3412126

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:19

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:09:22

US3412126

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:19

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:09:22

US3412126

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:19

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:09:22

US3412126

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:19

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '1'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:09:22

US3412126

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:19

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:09:22

US3412126

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:19

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:09:22

US3412126

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:19

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:09:22

US3412126

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:19

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:09:22

US3412126

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:19

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:09:22

US3412126

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:19

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:09:22

US3412126

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:19

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:09:22

US3412126

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:19

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '04 Aug 2020'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:09:34

US3412126

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered 'Aug 2020'	System	04 Aug 2020 20:09:34

US3412126

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered '2020'	System	04 Aug 2020 20:09:34

US3412126

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:19

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'Amendment 1 (1)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:09:34

US3412126

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:09:34

US3412126

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:19

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:09:34

US3412126

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:19

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:09:34

US3412126

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:19

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:09:34

US3412126

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:19

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 19:19:43

US3412126

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:19

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered '1'	System	04 Aug 2020 20:10:02

US3412126

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:10:02

US3412126

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:34:19

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:39:47

US3412126

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	(b) (4)	07 Aug 2020 14:42:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	07 Aug 2020 14:42:09
Data point term sent to Coder	System	07 Aug 2020 14:41:08
User entered 'Hypertension'	(b) (4), (b) (6)	07 Aug 2020 14:40:16

US3412126

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:40:16

US3412126

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:40:16

US3412126

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:40:16

US3412126

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:40:16

US3412126

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:40:16

US3412126

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:19

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered 'Jan 2010'	System	07 Aug 2020 14:40:16

US3412126

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:19

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered '2010'	System	07 Aug 2020 14:40:16

US3412126

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered empty.	System	07 Aug 2020 14:40:16

US3412126

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered empty.	System	07 Aug 2020 14:40:16

US3412126

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:34:19

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User closed query 'Per CDM RQ: Thank you for the response 'Per Source has shoulder + hips (2010).' Please confirm if condition start date should be updated to 2010, else clarify. ' (Site from DM). Query 'Per CDM RQ: Thank you for the response 'Per Source has shoulder + hips (2010).' Please confirm if condition start date should be updated to 2010, else clarify. ' answered with 'this date has been updated per query and confirmed in source that the date of onset was 2010' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 14:52:26
User opened query 'Per CDM RQ: Thank you for the response 'Per Source has shoulder + hips (2010).' Please confirm if condition start date should be updated to 2010, else clarify. ' (Site from DM). User closed query 'Per CDM re-query: Start date of this condition is UN UNK 2014 which is after the medication start date (CM #7 - UN UN 2010). Please review, reconcile and update the start date as appropriate else please clarify.' (Site from DM). Query 'Per CDM re-query: Start date of this condition is UN UNK 2014 which is after the medication start date (CM #7 - UN UN 2010). Please review, reconcile and update the start date as appropriate else please clarify.' answered with 'PER SOURCE HAS SHOULDERS + HIPS (2010) ' (Site from DM).	Steven Anderson (b) (4) (b) (4)	28 Jan 2021 20:19:13
User opened query 'Per CDM RQ: Thank you for the response 'Per Source has shoulder + hips (2010).' Please confirm if condition start date should be updated to 2010, else clarify. ' (Site from DM). User closed query 'Per CDM re-query: Start date of this condition is UN UNK 2014 which is after the medication start date (CM #7 - UN UN 2010). Please review, reconcile and update the start date as appropriate else please clarify.' (Site from DM). Query 'Per CDM re-query: Start date of this condition is UN UNK 2014 which is after the medication start date (CM #7 - UN UN 2010). Please review, reconcile and update the start date as appropriate else please clarify.' answered with 'PER SOURCE HAS SHOULDERS + HIPS (2010) ' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 18:10:44
User opened query 'Per CDM re-query: Start date of this condition is UN UNK 2014 which is after the medication start date (CM #7 - UN UN 2010). Please review, reconcile and update the start date as appropriate else please clarify.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 18:10:44
User opened query 'Per CDM re-query: Start date of this condition is UN UNK 2014 which is after the medication start date (CM #7 - UN UN 2010). Please review, reconcile and update the start date as appropriate else please clarify.' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 13:57:41
User opened query 'Per CDM re-query: Start date of this condition is UN UNK 2014 which is after the medication start date (CM #7 - UN UN 2010). Please review, reconcile and update the start date as appropriate else please clarify.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 04:25:59
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 09:03:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 09:03:24
Data point term sent to Coder	System	07 Aug 2020 14:41:08

US3412126

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:34:19

[Condition](#)

Audit	User	Time (GMT)
User entered 'Osteoarthritis Hips and shoulders'	(b) (4), (b) (6)	07 Aug 2020 14:40:35

US3412126

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:34:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'UN UNK 2010' reason for change: Data Entry Error	(b) (4)	
User entered 'UN UNK 2014' reason for change: Data Entry Error	Steven Anderson (b) (4)	28 Jan 2021 20:18:29
User entered 'UN UNK 2015'	(b) (4)	
	Melissa Fuson (b) (4)	26 Oct 2020 18:13:07
	(b) (4)	
	(b) (4), (b) (6)	07 Aug 2020 14:40:35

US3412126

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:34:19

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:40:35

US3412126

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:34:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:40:35

US3412126

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:40:35

US3412126

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:34:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:40:35

US3412126

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered 'Jan 2010'	System	28 Jan 2021 20:18:29
User entered 'Jan 2014'	System	26 Oct 2020 18:13:07
User entered 'Jan 2015'	System	07 Aug 2020 14:40:35

US3412126

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:34:19

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered '2010'	System	28 Jan 2021 20:18:29
User entered '2014'	System	26 Oct 2020 18:13:07
User entered '2015'	System	07 Aug 2020 14:40:35

US3412126

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered empty.	System	07 Aug 2020 14:40:35

US3412126

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered empty.	System	07 Aug 2020 14:40:35

US3412126

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:34:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\23.0.	Coder Import (b) (4)	07 Aug 2020 14:42:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	07 Aug 2020 14:42:10
Data point term sent to Coder	System	07 Aug 2020 14:41:09
User entered 'Anxiety'	(b) (4), (b) (6)	07 Aug 2020 14:40:49

US3412126

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'UN Mar 2015' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 18:13:30
User entered 'UN Mar 2020'	Melissa Fuson (b) (4)	07 Aug 2020 14:40:49
	(b) (4)	
	(b) (4), (b) (6)	

US3412126

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:34:19

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:40:49

US3412126

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:34:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:40:49

US3412126

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:40:49

US3412126

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:34:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:40:49

US3412126

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered 'Mar 2015'	System	26 Oct 2020 18:13:30
User entered 'Mar 2020'	System	07 Aug 2020 14:40:49

US3412126

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:34:19

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered '2015'	System	26 Oct 2020 18:13:30
User entered '2020'	System	07 Aug 2020 14:40:49

US3412126

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered empty.	System	07 Aug 2020 14:40:49

US3412126

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered empty.	System	07 Aug 2020 14:40:49

US3412126

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:34:19

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 15:32:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 15:32:34
Data point term sent to Coder	System	20 Oct 2020 15:31:53
User entered 'post menopausal'	Jacob sekinger (b) (4)	20 Oct 2020 15:31:00
	(b) (4)	

US3412126

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'un UNK 2010'	(b) (4) Jacob sekinger (b) (4) (b) (4)	20 Oct 2020 15:31:00

US3412126

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:34:19

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '0'	Jacob sekinger (b) (4)	20 Oct 2020 15:31:00

US3412126

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:34:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'Yes (Y)'	(b) (4) Jacob sekinger (b) (4) (b) (4)	20 Oct 2020 15:31:00

US3412126

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered empty.	Jacob sekinger (b) (4)	20 Oct 2020 15:31:00

US3412126

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:34:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '0'	Jacob sekinger (b) (4)	20 Oct 2020 15:31:00

US3412126

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:34:19

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered 'Jan 2010'	System	20 Oct 2020 15:31:00

US3412126

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:34:19

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered '2010'	System	20 Oct 2020 15:31:00

US3412126

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered empty.	System	20 Oct 2020 15:31:00

US3412126

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered empty.	System	20 Oct 2020 15:31:00

US3412126

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:34:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergic rhinitis - version MedDRA\23.0.	Coder Import (b) (4)	26 Oct 2020 17:11:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	26 Oct 2020 17:11:35
Data point term sent to Coder	System	26 Oct 2020 17:02:58
User entered 'ALLERGIC RHINITIS - SEASONAL'	Melissa Fuson (b) (4)	26 Oct 2020 17:02:28

US3412126

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	19 Feb 2021 03:55:44
Signature has been broken.	(b) (4) Steven Anderson (b) (4)	18 Feb 2021 15:03:58
User entered 'UN UNK 2017' reason for change: Data Entry Error	(b) (4) Steven Anderson (b) (4)	18 Feb 2021 15:03:58
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'UN UNK 2019'	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:02:28

US3412126

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:34:19

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '0'	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:02:28

US3412126

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:34:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'Yes (Y)'	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:02:28

US3412126

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered empty.	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:02:28

US3412126

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:34:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '0'	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:02:28

US3412126

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered 'Jan 2017'	System	18 Feb 2021 15:03:58
User entered 'Jan 2019'	System	26 Oct 2020 17:02:28

US3412126

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:34:19

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered '2017'	System	18 Feb 2021 15:03:58
User entered '2019'	System	26 Oct 2020 17:02:28

US3412126

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered empty.	System	26 Oct 2020 17:02:28

US3412126

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered empty.	System	26 Oct 2020 17:02:28

US3412126

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:34:19

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 14:52:34
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'subject has not reported any con med for this condition. per medical records obtained the subject does not have anything reported on there either. site will update if any other information becomes available' (Site from DM).	Steven Anderson (b) (4) (b) (4)	28 Jan 2021 20:22:17
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 13:48:13
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Bronchitis chronic, LLT: Chronic bronchitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 17:14:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 17:14:38
Data point term sent to Coder	System	26 Oct 2020 17:04:02
User entered 'CHRONIC BRONCHITIS'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:03:36

US3412126

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'UN UNK 2010'	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:03:36

US3412126

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:34:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '0'	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:03:36

US3412126

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:34:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'Yes (Y)'	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:03:36

US3412126

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered empty.	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:03:36

US3412126

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:34:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '0'	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:03:36

US3412126

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:34:19

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered 'Jan 2010'	System	26 Oct 2020 17:03:36

US3412126

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:34:19

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered '2010'	System	26 Oct 2020 17:03:36

US3412126

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered empty.	System	26 Oct 2020 17:03:36

US3412126

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered empty.	System	26 Oct 2020 17:03:36

US3412126

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:34:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related disorders NEC, PT: Periarthritis, LLT: Frozen shoulder - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 22:22:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 22:22:32
Data point term sent to Coder	System	26 Oct 2020 17:05:02
User entered 'FROZEN SHOULDER - BILATERAL'	Melissa Fuson (b) (4)	26 Oct 2020 17:04:07

US3412126

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'UN UNK 2017'	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:04:07

US3412126

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:34:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '0'	(b) (4) Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:04:07

US3412126

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:34:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'Yes (Y)'	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:04:07

US3412126

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:04:07

US3412126

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:34:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '0'	(b) (4) Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:04:07

US3412126

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered 'Jan 2017'	System	26 Oct 2020 17:04:07

US3412126

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered '2017'	System	26 Oct 2020 17:04:07

US3412126

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered empty.	System	26 Oct 2020 17:04:07

US3412126

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered empty.	System	26 Oct 2020 17:04:07

US3412126

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:34:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteoporosis, LLT: Osteoporosis - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	26 Oct 2020 17:44:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	26 Oct 2020 17:44:29
Data point term sent to Coder	System	26 Oct 2020 17:15:15
User entered 'OSTEOPEROSIS'	Melissa Fuson (b) (4)	26 Oct 2020 17:14:25
	(b) (4)	

US3412126

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
Signature has been broken.	(b) (4) Andrea Newlands (b) (4)	05 Apr 2021 16:05:40
User entered 'UN UNK 2010' reason for change: Data Entry Error	(b) (4) Andrea Newlands (b) (4)	05 Apr 2021 16:05:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'UN UNK 2015'	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:14:25

US3412126

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:34:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '0'	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:14:25

US3412126

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:34:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'Yes (Y)'	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:14:25

US3412126

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered empty.	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:14:25

US3412126

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:34:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '0'	(b) (4) Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:14:25

US3412126

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered 'Jan 2010'	System	05 Apr 2021 16:05:40
User entered 'Jan 2015'	System	26 Oct 2020 17:14:25

US3412126

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:34:19

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered '2010'	System	05 Apr 2021 16:05:40
User entered '2015'	System	26 Oct 2020 17:14:25

US3412126

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered empty.	System	26 Oct 2020 17:14:25

US3412126

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered empty.	System	26 Oct 2020 17:14:25

US3412126

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:34:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
User coded data point as SOC: Social circumstances, HLGHT: Lifestyle issues, HLT: Tobacco use, PT: Tobacco user, LLT: Smoker - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 20:23:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 20:23:32
Data point term sent to Coder	System	15 Mar 2021 20:22:31
User entered 'Smoking'	Steven Anderson (b) (4)	15 Mar 2021 20:22:12

US3412126

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4) (b) (4)	12 Apr 2021 14:35:05
User entered 'un UNK 1980'	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 20:22:12

US3412126

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:34:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
User entered '0'	Steven Anderson (b) (4)	15 Mar 2021 20:22:12

US3412126

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:34:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4) (b) (4)	12 Apr 2021 14:35:05
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 20:22:12

US3412126

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
User entered empty.	(b) (4) Steven Anderson (b) (4)	15 Mar 2021 20:22:12

US3412126

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:34:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4) (b) (4)	12 Apr 2021 14:35:05
User entered '0'	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 20:22:12

US3412126

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:34:19

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered 'Jan 1980'	System	15 Mar 2021 20:22:12

US3412126

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered '1980'	System	15 Mar 2021 20:22:12

US3412126

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered empty.	System	15 Mar 2021 20:22:12

US3412126

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered empty.	System	15 Mar 2021 20:22:12

US3412126

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:36
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:43:48

US3412126

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:36
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '04 Aug 2020'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:43:48

US3412126

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:36
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '15:09'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:43:48

US3412126

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:36
User entered '04 Aug 2020 15:09'	System	07 Aug 2020 14:43:48

US3412126

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:36
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '149.8' cm	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:43:48
DataPoint set to visible.	System	04 Aug 2020 20:10:02

US3412126

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:36
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '48.2' kg	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:43:48
DataPoint set to visible.	System	04 Aug 2020 20:10:02

US3412126

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:36
Amendment Manager: User entered '21.47946'	System	16 Sep 2020 23:43:02
User entered '21.5'	System	07 Aug 2020 14:43:48
DataPoint set to visible.	System	04 Aug 2020 20:10:02

US3412126

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:36
User entered 'kg/m2'	System	07 Aug 2020 14:43:48
DataPoint set to visible.	System	04 Aug 2020 20:10:02

US3412126

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:36
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User closed query 'Per CDM: Temperature is recorded as ND however unit is provided. Please review and update. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Jan 2021 13:45:02
Query 'Per CDM: Temperature is recorded as ND however unit is provided. Please review and update. ' answered with 'TOOK OUT - LEFT IN ERROR' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	05 Jan 2021 20:16:53
User entered missing code ND - Not Done; reason for change Data Entry Error	Melissa Fuson (b) (4) (b) (4)	05 Jan 2021 20:16:47
User opened query 'Per CDM: Temperature is recorded as ND however unit is provided. Please review and update. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 18:51:57
User closed query 'Per CDM, For Screening and VID1 on the same day, as per CCG pg 15-16, Temperature, Pulse, Respiratory Rate, Systolic BP and Diastolic BP has to be recorded as 'ND' in the Screening Page and these values has to be recorded in the Pre Dose Vital sign VID1 page. Please update accordingly else clarify. Thank you' (Site from DM).		23 Sep 2020 17:53:02
User entered missing code ND - Not Done; reason for change Data Entry Error	Mylene Asmar-Rios (b) (4)	22 Sep 2020 19:25:04
Query 'Per CDM, For Screening and VID1 on the same day, as per CCG pg 15-16, Temperature, Pulse, Respiratory Rate, Systolic BP and Diastolic BP has to be recorded as 'ND' in the Screening Page and these values has to be recorded in the Pre Dose Vital sign VID1 page. Please update accordingly else clarify. Thank you' answered with 'V1 WILL BE DONE ON A DIFFERENT DAY' (Site from DM).	Mylene Asmar-Rios (b) (4)	22 Sep 2020 19:19:56
User opened query 'Per CDM, For Screening and VID1 on the same day, as per CCG pg 15-16, Temperature, Pulse, Respiratory Rate, Systolic BP and Diastolic BP has to be recorded as 'ND' in the Screening Page and these values has to be recorded in the Pre Dose Vital sign VID1 page. Please update accordingly else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 06:25:47
User entered '37.1' C	(b) (4), (b) (6)	07 Aug 2020 14:43:48

US3412126

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:36
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered empty; reason for change Data Entry Error	(b) (4)	22 Sep 2020 19:25:04
User entered 'Oral (Oral)'	Mylene Asmar-Rios (b) (4), (b) (6)	07 Aug 2020 14:43:48

US3412126

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:36
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:43:48

US3412126

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:36
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	22 Sep 2020 19:25:04
User entered '84'	(b) (4), (b) (6)	07 Aug 2020 14:43:48

US3412126

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:36
User entered 'bpm'	System	07 Aug 2020 14:43:48

US3412126

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:36
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	22 Sep 2020 19:25:04
User entered '16'	(b) (4), (b) (6)	07 Aug 2020 14:43:48

US3412126

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:36
User entered 'breaths/min'	System	07 Aug 2020 14:43:48

US3412126

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:36
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	22 Sep 2020 19:25:04
User entered '114'	(b) (4), (b) (6)	07 Aug 2020 14:43:48

US3412126

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:36
User entered 'mmHg'	System	07 Aug 2020 14:43:48

US3412126

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:36
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	22 Sep 2020 19:25:04
User entered '74'	(b) (4), (b) (6)	07 Aug 2020 14:43:48

US3412126

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:36
User entered 'mmHg'	System	07 Aug 2020 14:43:48

US3412126

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:36

US3412126

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:36

US3412126

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:42:42

US3412126

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:19

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '04 Aug 2020'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:42:42

US3412126

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:34:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '04 Aug 2020'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:43:13

US3412126

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:34:19

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:43:13

US3412126

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:34:19

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 12:24:13
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' answered with 'updated. ' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	20 Oct 2020 15:31:09
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 05:05:30
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4), (b) (6)	07 Aug 2020 14:43:13

US3412126

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:34:19

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:43:13

US3412126

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:34:19

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:43:13

US3412126

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:34:19

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:43:13

US3412126

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:34:19

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:43:13

US3412126

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:34:19

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:43:13

US3412126

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:19

[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 22:54:36
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:42:22

US3412126

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:19

[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 22:54:36
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:42:22

US3412126

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:19

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 22:54:36
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:42:22

US3412126

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:19

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 22:54:36
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:42:22

US3412126

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:19

[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 22:54:36
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:42:22

US3412126

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:19

[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 22:54:36
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:42:22

US3412126

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:19

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 22:54:36
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:42:22

US3412126

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:19

[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 22:54:36
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:42:22

US3412126

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:19

[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 22:54:36
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:42:22

US3412126

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:19

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 22:54:36
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:42:22

US3412126

Folder: Screening

Form: Risk of Exposure

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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 22:54:36
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:42:22

US3412126

Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:36
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	22 Sep 2020 19:22:45
User entered 'No (N)'	Mylene Asmar-Rios (b) (4), (b) (6)	07 Aug 2020 14:42:22

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:36
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered (b) (6) FEMALE GOES TO GROCERY STORE, RESTAURANTS AND LIVES WITH ESSENTIAL WORKER' reason for change:	(b) (4)	22 Sep 2020 19:22:45
Data Entry Error	Mylene Asmar-Rios	
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	07 Aug 2020 14:42:22

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Folder: Screening

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:36
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:42:22

US3412126

Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:36
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:42:22

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:36
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:42:22

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Folder: Screening

Form: Risk of Exposure

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[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 22:54:36
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '1'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:42:22

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Folder: Screening

Form: Risk of Exposure

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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 22:54:36
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:42:22

US3412126

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:36
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:42:22

US3412126

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:19

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:36
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '1' reason for change: Data Entry Error	(b) (4) Mylene Asmar-Rios	22 Sep 2020 19:22:45
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:42:22

US3412126

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:19

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:54:36
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'LIVES IN HIGH RISK COUNTY'	(b) (4)	22 Sep 2020 19:22:45
reason for change: Data Entry Error	Mylene Asmar-Rios	
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	07 Aug 2020 14:42:22

US3412126

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:34:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:10:19

US3412126

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:34:19

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered '04 Aug 2020'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:10:19

US3412126

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:10:19

US3412126

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:34:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User entered 'VISIT1'	System	04 Aug 2020 20:10:19

US3412126

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered '04 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 19:54:16

US3412126

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 02:04:52
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:04:52
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Aug 2020 19:54:16
User entered '100876' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 19:54:16

US3412126

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 19:54:16

US3412126

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:19

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)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:09:02

US3412126

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:19

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)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:09:02

US3412126

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:09:02

US3412126

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:19

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:09:02

US3412126

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:19

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:09:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:19

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:19

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:19

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:45:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:19

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:45:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User accepted default value 'Pre-Dose (PREDOSE)'		07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	22 Sep 2020 19:26:10
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 14:45:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered '04 Aug 2020' reason for change: Data Entry Error	(b) (4)	22 Sep 2020 19:26:10
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 14:45:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered '15:09' reason for change: Data Entry Error	(b) (4)	22 Sep 2020 19:26:10
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 14:45:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User entered '04 Aug 2020 15:09'	System	22 Sep 2020 19:26:10
User entered empty.	System	07 Aug 2020 14:45:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered '37.1' C reason for change: Data Entry Error	(b) (4)	22 Sep 2020 19:26:10
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 14:45:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	22 Sep 2020 19:26:10
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 14:45:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:45:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered '84' reason for change: Data Entry Error	(b) (4)	22 Sep 2020 19:26:10
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 14:45:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User entered 'bpm'	System	22 Sep 2020 19:26:10
User entered empty.	System	07 Aug 2020 14:45:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered '16' reason for change: Data Entry Error	(b) (4)	22 Sep 2020 19:26:10
User entered empty.	Mylene Asmar-Rios (b) (4)	07 Aug 2020 14:45:19
	(b) (4), (b) (6)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User entered 'breaths/min'	System	22 Sep 2020 19:26:10
User entered empty.	System	07 Aug 2020 14:45:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered '114' reason for change: Data Entry Error	(b) (4)	22 Sep 2020 19:26:10
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 14:45:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User entered 'mmHg'	System	22 Sep 2020 19:26:10
User entered empty.	System	07 Aug 2020 14:45:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered '74' reason for change: Data Entry Error	(b) (4)	22 Sep 2020 19:26:10
User entered empty.	Mylene Asmar-Rios (b) (4)	07 Aug 2020 14:45:19
	(b) (4), (b) (6)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User entered 'mmHg'	System	22 Sep 2020 19:26:10
User entered empty.	System	07 Aug 2020 14:45:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:19

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:19

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:45:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:45:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered '04 Aug 2020'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:45:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:12:21
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		07 Aug 2020 14:45:19
User entered '16:53'	(b) (4), (b) (6)	07 Aug 2020 14:45:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User entered '04 Aug 2020 16:53'	System	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered '66'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User entered 'bpm'	System	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered '16'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User entered 'breaths/min'	System	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered '132'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User entered 'mmHg'	System	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered '70'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User entered 'mmHg'	System	07 Aug 2020 14:45:19

US3412126

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:44:01

US3412126

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:19

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:44:01

US3412126

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:23:53

US3412126

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:19

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:23:53

US3412126

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:19

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)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:23:53

US3412126

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:19

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User entered 'MRNA-1273 OR PLACEBO'	System	04 Aug 2020 20:23:53

US3412126

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:19

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered '04 Aug 2020'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:23:53

US3412126

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:19

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered '16:15'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:23:53

US3412126

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:19

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User entered '04 Aug 2020 16:15'	System	04 Aug 2020 20:23:53

US3412126

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:19

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:23:53

US3412126

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:19

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User entered 'ONCE'	System	04 Aug 2020 20:23:53

US3412126

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:19

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User entered 'INTRAMUSCULAR'	System	04 Aug 2020 20:23:53

US3412126

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:44:28

US3412126

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:19

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered '04 Aug 2020'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:44:28

US3412126

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered '15:40'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:44:28

US3412126

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User entered '04 Aug 2020 15:40'	System	07 Aug 2020 14:44:28

US3412126

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:34:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered '04 Aug 2020'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:44:41

US3412126

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:34:19

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	07 Aug 2020 14:44:41

US3412126

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:34:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:44:41

US3412126

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:34:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered '15:46'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:44:41

US3412126

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:34:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User entered '04 Aug 2020 15:46'	System	07 Aug 2020 14:44:41

US3412126

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:34:19

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	07 Aug 2020 14:44:41

US3412126

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:34:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:44:41

US3412126

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:34:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:44:41

US3412126

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:34:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User entered empty.	System	07 Aug 2020 14:44:41

US3412126

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:34:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 14:44:05

US3412126

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:34:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User entered '1'	System	07 Aug 2020 14:44:05

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:34:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-04T16:59:01', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '590fa793-713c-44e1-8ba7-9c9df32122e7'	System	04 Aug 2020 20:59:34
User entered 'Yes (Y)'	System	04 Aug 2020 20:59:34

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:34:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-04T16:59:09', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '590fa793-713c-44e1-8ba7-9c9df32122e7'	System	04 Aug 2020 20:59:34
User entered '98.1'	System	04 Aug 2020 20:59:34

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-04T16:59:25', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '590fa793-713c-44e1-8ba7-9c9df32122e7'	System	04 Aug 2020 20:59:34
User entered 'No (N)'	System	04 Aug 2020 20:59:34

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-04T16:59:31', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '590fa793-713c-44e1-8ba7-9c9df32122e7'	System	04 Aug 2020 20:59:34
User entered '04 Aug 2020 16:59'	System	04 Aug 2020 20:59:34

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '04 Aug 2020 16:35'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '04 Aug 2020 19:05'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:19

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '04 Aug 2020 20:00'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 2'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-05T19:27:24', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '8457c6cd-db5d-4b82-ad3d-90b99f964b6c'	System	05 Aug 2020 23:28:17
User entered 'Yes (Y)'	System	05 Aug 2020 23:28:17

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-05T19:27:33', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '8457c6cd-db5d-4b82-ad3d-90b99f964b6c'	System	05 Aug 2020 23:28:17
User entered '100.6'	System	05 Aug 2020 23:28:17

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-05T19:27:42', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '8457c6cd-db5d-4b82-ad3d-90b99f964b6c'	System	05 Aug 2020 23:28:17
User entered 'Yes (Y)'	System	05 Aug 2020 23:28:17

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant was contacted' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 04:58:17
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Mylene Asmar-Rios (b) (4)	01 Oct 2020 14:29:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-05T19:27:52', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '8457c6cd-db5d-4b82-ad3d-90b99f964b6c'	System	05 Aug 2020 23:28:17
User entered '1'	System	05 Aug 2020 23:28:17

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:19

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-05T19:27:52', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '8457c6cd-db5d-4b82-ad3d-90b99f964b6c'	System	05 Aug 2020 23:28:17
User entered '0'	System	05 Aug 2020 23:28:17

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-05T19:28:12', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '8457c6cd-db5d-4b82-ad3d-90b99f964b6c'	System	05 Aug 2020 23:28:17
User entered '05 Aug 2020 19:28'	System	05 Aug 2020 23:28:17

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 3'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-06T19:32:30', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'b9fc11d6-c462-460b-9cc4-5ffbb9e55b70'	System	06 Aug 2020 23:33:12
User entered 'Yes (Y)'	System	06 Aug 2020 23:33:12

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:19

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-06T19:32:37', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'b9fc11d6-c462-460b-9cc4-5ffbb9e55b70'	System	06 Aug 2020 23:33:12
User entered '99.8'	System	06 Aug 2020 23:33:12

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-06T19:32:48', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'b9fc11d6-c462-460b-9cc4-5ffbb9e55b70'	System	06 Aug 2020 23:33:12
User entered 'Yes (Y)'	System	06 Aug 2020 23:33:12

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant was contacted ' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 04:58:21
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Mylene Asmar-Rios (b) (4)	01 Oct 2020 14:33:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-06T19:33:03', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'b9fc11d6-c462-460b-9cc4-5ffbb9e55b70'	System	06 Aug 2020 23:33:12
User entered '1'	System	06 Aug 2020 23:33:12

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:19

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-06T19:33:03', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'b9fc11d6-c462-460b-9cc4-5ffbb9e55b70'	System	06 Aug 2020 23:33:12
User entered '0'	System	06 Aug 2020 23:33:12

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-06T19:33:09', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'b9fc11d6-c462-460b-9cc4-5ffbb9e55b70'	System	06 Aug 2020 23:33:12
User entered '06 Aug 2020 19:33'	System	06 Aug 2020 23:33:12

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 4'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-07T19:35:14', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'c59984cb-9379-44e1-9a8e-53a44a690087'	System	07 Aug 2020 23:35:39
User entered 'Yes (Y)'	System	07 Aug 2020 23:35:39

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-07T19:35:21', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'c59984cb-9379-44e1-9a8e-53a44a690087'	System	07 Aug 2020 23:35:39
User entered '100.4'	System	07 Aug 2020 23:35:39

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-07T19:35:25', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'c59984cb-9379-44e1-9a8e-53a44a690087'	System	07 Aug 2020 23:35:39
User entered 'Yes (Y)'	System	07 Aug 2020 23:35:39

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant was contacted' (Site from System).	(b) (4)	12 Oct 2020 04:58:25
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Mylene Asmar-Rios (b) (4)	01 Oct 2020 14:34:19
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	07 Aug 2020 23:35:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-07T19:35:33', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'c59984cb-9379-44e1-9a8e-53a44a690087'	System	07 Aug 2020 23:35:39
User entered '1'	System	07 Aug 2020 23:35:39

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:19

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-07T19:35:33', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'c59984cb-9379-44e1-9a8e-53a44a690087'	System	07 Aug 2020 23:35:39
User entered '0'	System	07 Aug 2020 23:35:39

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-07T19:35:37', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'c59984cb-9379-44e1-9a8e-53a44a690087'	System	07 Aug 2020 23:35:39
User entered '07 Aug 2020 19:35'	System	07 Aug 2020 23:35:39

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 5'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:34:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-08T19:13:25', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '89ec4503-a5a7-445a-aa6b-64eadeebd3fc'	System	08 Aug 2020 23:13:45
User entered 'Yes (Y)'	System	08 Aug 2020 23:13:45

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:34:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-08T19:13:34', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '89ec4503-a5a7-445a-aa6b-64eadeebd3fc'	System	08 Aug 2020 23:13:45
User entered '99.5'	System	08 Aug 2020 23:13:45

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-08T19:13:39', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '89ec4503-a5a7-445a-aa6b-64eadeebd3fc'	System	08 Aug 2020 23:13:45
User entered 'No (N)'	System	08 Aug 2020 23:13:45

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-08T19:13:43', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '89ec4503-a5a7-445a-aa6b-64eadeebd3fc'	System	08 Aug 2020 23:13:45
User entered '08 Aug 2020 19:13'	System	08 Aug 2020 23:13:45

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 6'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:34:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-09T19:25:54', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '257321e1-c774-462f-9a37-8c26f464c5cb'	System	09 Aug 2020 23:26:15
User entered 'Yes (Y)'	System	09 Aug 2020 23:26:15

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:34:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-09T19:26:01', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '257321e1-c774-462f-9a37-8c26f464c5cb'	System	09 Aug 2020 23:26:15
User entered '98.3'	System	09 Aug 2020 23:26:15

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-09T19:26:05', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '257321e1-c774-462f-9a37-8c26f464c5cb'	System	09 Aug 2020 23:26:15
User entered 'No (N)'	System	09 Aug 2020 23:26:15

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-09T19:26:09', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '257321e1-c774-462f-9a37-8c26f464c5cb'	System	09 Aug 2020 23:26:15
User entered '09 Aug 2020 19:26'	System	09 Aug 2020 23:26:15

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 7'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:34:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-10T19:17:20', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'add5080f-5d3b-4432-8fc3-1fba84e5ef8b'	System	10 Aug 2020 23:17:47
User entered 'Yes (Y)'	System	10 Aug 2020 23:17:47

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:34:19

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-10T19:17:26', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'add5080f-5d3b-4432-8fc3-1fba84e5ef8b'	System	10 Aug 2020 23:17:47
User entered '99.2'	System	10 Aug 2020 23:17:47

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-10T19:17:30', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'add5080f-5d3b-4432-8fc3-1fba84e5ef8b'	System	10 Aug 2020 23:17:47
User entered 'Yes (Y)'	System	10 Aug 2020 23:17:47

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'patient was contacted' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 04:58:36
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Mylene Asmar-Rios (b) (4)	01 Oct 2020 14:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-10T19:17:38', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'add5080f-5d3b-4432-8fc3-1fba84e5ef8b'	System	10 Aug 2020 23:17:47
User entered '1'	System	10 Aug 2020 23:17:47

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:34:19

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-10T19:17:38', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'add5080f-5d3b-4432-8fc3-1fba84e5ef8b'	System	10 Aug 2020 23:17:47
User entered '0'	System	10 Aug 2020 23:17:47

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-10T19:17:42', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'add5080f-5d3b-4432-8fc3-1fba84e5ef8b'	System	10 Aug 2020 23:17:47
User entered '10 Aug 2020 19:17'	System	10 Aug 2020 23:17:47

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
Data entry locked.	System	10 Aug 2020 23:17:47
User entered 'Day 8'	System	10 Aug 2020 23:17:47

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:34:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-11T19:38:55', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '660ba066-4895-4d8f-b71f-524dbea8d66f'	System	11 Aug 2020 23:39:14
User entered 'Yes (Y)'	System	11 Aug 2020 23:39:14

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:34:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-11T19:39:01', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '660ba066-4895-4d8f-b71f-524dbea8d66f'	System	11 Aug 2020 23:39:14
User entered '98.1'	System	11 Aug 2020 23:39:14

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-11T19:39:06', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '660ba066-4895-4d8f-b71f-524dbea8d66f'	System	11 Aug 2020 23:39:14
User entered 'No (N)'	System	11 Aug 2020 23:39:14

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-11T19:39:10', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '660ba066-4895-4d8f-b71f-524dbea8d66f'	System	11 Aug 2020 23:39:14
User entered '11 Aug 2020 19:39'	System	11 Aug 2020 23:39:14

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 23:17:47

US3412126

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 17:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 23:17:47

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-04T17:00:56', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'c4089cac-7d16-4bf2-9b88-4bf185120559'	System	04 Aug 2020 21:01:17
User entered 'None (1)'	System	04 Aug 2020 21:01:17

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-04T17:01:00', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'c4089cac-7d16-4bf2-9b88-4bf185120559'	System	04 Aug 2020 21:01:17
User entered 'No (N)'	System	04 Aug 2020 21:01:17

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-04T17:01:03', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'c4089cac-7d16-4bf2-9b88-4bf185120559'	System	04 Aug 2020 21:01:17
User entered 'No (N)'	System	04 Aug 2020 21:01:17

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-04T17:01:07', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'c4089cac-7d16-4bf2-9b88-4bf185120559'	System	04 Aug 2020 21:01:17
User entered 'None (1)'	System	04 Aug 2020 21:01:17

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-04T17:01:15', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'c4089cac-7d16-4bf2-9b88-4bf185120559'	System	04 Aug 2020 21:01:17
User entered '04 Aug 2020 17:01'	System	04 Aug 2020 21:01:17

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '04 Aug 2020 16:35'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '04 Aug 2020 19:05'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:19

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:19

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '04 Aug 2020 20:00'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 2'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-05T19:28:31', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'e8c41f48-2102-4251-b2cc-b5724b683af7'	System	05 Aug 2020 23:29:06
User entered 'Does not interfere with activity (2)'	System	05 Aug 2020 23:29:06

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-05T19:28:36', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'e8c41f48-2102-4251-b2cc-b5724b683af7'	System	05 Aug 2020 23:29:06
User entered 'No (N)'	System	05 Aug 2020 23:29:06

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-05T19:28:43', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'e8c41f48-2102-4251-b2cc-b5724b683af7'	System	05 Aug 2020 23:29:06
User entered 'No (N)'	System	05 Aug 2020 23:29:06

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-05T19:28:51', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'e8c41f48-2102-4251-b2cc-b5724b683af7'	System	05 Aug 2020 23:29:06
User entered 'None (1)'	System	05 Aug 2020 23:29:06

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-05T19:29:01', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'e8c41f48-2102-4251-b2cc-b5724b683af7'	System	05 Aug 2020 23:29:06
User entered '05 Aug 2020 19:29'	System	05 Aug 2020 23:29:06

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 3'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-06T19:33:24', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'adf1a9b2-a6c9-43c1-af4a-aec3d5783352'	System	06 Aug 2020 23:33:45
User entered 'Does not interfere with activity (2)'	System	06 Aug 2020 23:33:45

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-06T19:33:28', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'adf1a9b2-a6c9-43c1-af4a-aec3d5783352'	System	06 Aug 2020 23:33:45
User entered 'No (N)'	System	06 Aug 2020 23:33:45

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-06T19:33:32', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'adf1a9b2-a6c9-43c1-af4a-aec3d5783352'	System	06 Aug 2020 23:33:45
User entered 'No (N)'	System	06 Aug 2020 23:33:45

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-06T19:33:39', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'adf1a9b2-a6c9-43c1-af4a-aec3d5783352'	System	06 Aug 2020 23:33:45
User entered 'None (1)'	System	06 Aug 2020 23:33:45

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-06T19:33:42', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'adf1a9b2-a6c9-43c1-af4a-aec3d5783352'	System	06 Aug 2020 23:33:45
User entered '06 Aug 2020 19:33'	System	06 Aug 2020 23:33:45

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 4'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-07T19:35:50', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '0bb61d36-84f7-415b-af57-e84488e4c5c0'	System	07 Aug 2020 23:36:06
User entered 'None (1)'	System	07 Aug 2020 23:36:06

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-07T19:35:47', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '0bb61d36-84f7-415b-af57-e84488e4c5c0'	System	07 Aug 2020 23:36:06
User entered 'No (N)'	System	07 Aug 2020 23:36:06

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-07T19:35:54', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '0bb61d36-84f7-415b-af57-e84488e4c5c0'	System	07 Aug 2020 23:36:06
User entered 'No (N)'	System	07 Aug 2020 23:36:06

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-07T19:35:57', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '0bb61d36-84f7-415b-af57-e84488e4c5c0'	System	07 Aug 2020 23:36:06
User entered 'None (1)'	System	07 Aug 2020 23:36:06

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-07T19:36:03', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '0bb61d36-84f7-415b-af57-e84488e4c5c0'	System	07 Aug 2020 23:36:06
User entered '07 Aug 2020 19:36'	System	07 Aug 2020 23:36:06

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 5'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-08T19:13:50', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'e52c254a-a81c-429e-99b9-a32dc01ddc50'	System	08 Aug 2020 23:14:07
User entered 'None (1)'	System	08 Aug 2020 23:14:07

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-08T19:13:54', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'e52c254a-a81c-429e-99b9-a32dc01ddc50'	System	08 Aug 2020 23:14:07
User entered 'No (N)'	System	08 Aug 2020 23:14:07

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-08T19:13:57', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'e52c254a-a81c-429e-99b9-a32dc01ddc50'	System	08 Aug 2020 23:14:07
User entered 'No (N)'	System	08 Aug 2020 23:14:07

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-08T19:14:01', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'e52c254a-a81c-429e-99b9-a32dc01ddc50'	System	08 Aug 2020 23:14:07
User entered 'None (1)'	System	08 Aug 2020 23:14:07

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-08T19:14:03', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'e52c254a-a81c-429e-99b9-a32dc01ddc50'	System	08 Aug 2020 23:14:07
User entered '08 Aug 2020 19:14'	System	08 Aug 2020 23:14:07

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 6'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-09T19:26:16', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'd4878acc-551b-4e61-a40b-032ea379d01e'	System	09 Aug 2020 23:26:36
User entered 'None (1)'	System	09 Aug 2020 23:26:36

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-09T19:26:20', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'd4878acc-551b-4e61-a40b-032ea379d01e'	System	09 Aug 2020 23:26:36
User entered 'No (N)'	System	09 Aug 2020 23:26:36

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-09T19:26:24', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'd4878acc-551b-4e61-a40b-032ea379d01e'	System	09 Aug 2020 23:26:36
User entered 'No (N)'	System	09 Aug 2020 23:26:36

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-09T19:26:27', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'd4878acc-551b-4e61-a40b-032ea379d01e'	System	09 Aug 2020 23:26:36
User entered 'None (1)'	System	09 Aug 2020 23:26:36

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-09T19:26:32', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'd4878acc-551b-4e61-a40b-032ea379d01e'	System	09 Aug 2020 23:26:36
User entered '09 Aug 2020 19:26'	System	09 Aug 2020 23:26:36

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 7'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-10T19:17:47', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '39f45b92-e7e0-4b5a-be88-f80b65c8b364'	System	10 Aug 2020 23:18:10
User entered 'None (1)'	System	10 Aug 2020 23:18:10

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-10T19:17:53', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '39f45b92-e7e0-4b5a-be88-f80b65c8b364'	System	10 Aug 2020 23:18:10
User entered 'No (N)'	System	10 Aug 2020 23:18:10

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-10T19:17:56', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '39f45b92-e7e0-4b5a-be88-f80b65c8b364'	System	10 Aug 2020 23:18:10
User entered 'No (N)'	System	10 Aug 2020 23:18:10

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-10T19:18:00', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '39f45b92-e7e0-4b5a-be88-f80b65c8b364'	System	10 Aug 2020 23:18:10
User entered 'None (1)'	System	10 Aug 2020 23:18:10

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-10T19:18:04', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '39f45b92-e7e0-4b5a-be88-f80b65c8b364'	System	10 Aug 2020 23:18:10
User entered '10 Aug 2020 19:18'	System	10 Aug 2020 23:18:10

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-04T17:01:25', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '84134fb0-9f23-4446-a028-4230b2011e2a'	System	04 Aug 2020 21:02:13
User entered 'None (0)'	System	04 Aug 2020 21:02:13

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-04T17:01:31', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '84134fb0-9f23-4446-a028-4230b2011e2a'	System	04 Aug 2020 21:02:13
User entered 'No interference with activity (1)'	System	04 Aug 2020 21:02:13

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-04T17:01:40', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '84134fb0-9f23-4446-a028-4230b2011e2a'	System	04 Aug 2020 21:02:13
User entered 'None (0)'	System	04 Aug 2020 21:02:13

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-04T17:01:47', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '84134fb0-9f23-4446-a028-4230b2011e2a'	System	04 Aug 2020 21:02:13
User entered 'None (0)'	System	04 Aug 2020 21:02:13

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-04T17:01:53', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '84134fb0-9f23-4446-a028-4230b2011e2a'	System	04 Aug 2020 21:02:13
User entered 'None (0)'	System	04 Aug 2020 21:02:13

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-04T17:01:58', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '84134fb0-9f23-4446-a028-4230b2011e2a'	System	04 Aug 2020 21:02:13
User entered 'None (0)'	System	04 Aug 2020 21:02:13

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-04T17:02:03', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '84134fb0-9f23-4446-a028-4230b2011e2a'	System	04 Aug 2020 21:02:13
User entered 'No (N)'	System	04 Aug 2020 21:02:13

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-04T17:02:09', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '84134fb0-9f23-4446-a028-4230b2011e2a'	System	04 Aug 2020 21:02:13
User entered '04 Aug 2020 17:02'	System	04 Aug 2020 21:02:13

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '04 Aug 2020 16:35'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '04 Aug 2020 19:05'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '04 Aug 2020 20:00'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 2'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-05T19:29:10', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '91532e11-6953-4e2f-a180-160f90d985d3'	System	05 Aug 2020 23:30:15
User entered 'None (0)'	System	05 Aug 2020 23:30:15

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-05T19:29:22', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '91532e11-6953-4e2f-a180-160f90d985d3'	System	05 Aug 2020 23:30:15
User entered 'None (0)'	System	05 Aug 2020 23:30:15

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-05T19:29:37', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '91532e11-6953-4e2f-a180-160f90d985d3'	System	05 Aug 2020 23:30:15
User entered 'None (0)'	System	05 Aug 2020 23:30:15

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-05T19:29:42', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '91532e11-6953-4e2f-a180-160f90d985d3'	System	05 Aug 2020 23:30:15
User entered 'None (0)'	System	05 Aug 2020 23:30:15

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-05T19:29:51', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '91532e11-6953-4e2f-a180-160f90d985d3'	System	05 Aug 2020 23:30:15
User entered 'None (0)'	System	05 Aug 2020 23:30:15

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-05T19:29:59', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '91532e11-6953-4e2f-a180-160f90d985d3'	System	05 Aug 2020 23:30:15
User entered 'Some interference with activity not requiring medical attention (2)'	System	05 Aug 2020 23:30:15

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-05T19:30:08', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '91532e11-6953-4e2f-a180-160f90d985d3'	System	05 Aug 2020 23:30:15
User entered 'No (N)'	System	05 Aug 2020 23:30:15

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-05T19:30:12', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '91532e11-6953-4e2f-a180-160f90d985d3'	System	05 Aug 2020 23:30:15
User entered '05 Aug 2020 19:30'	System	05 Aug 2020 23:30:15

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 3'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-06T19:33:53', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '851af619-a89e-498b-bd6c-29710ccc58fb'	System	06 Aug 2020 23:34:45
User entered 'None (0)'	System	06 Aug 2020 23:34:45

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-06T19:34:03', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '851af619-a89e-498b-bd6c-29710ccc58fb'	System	06 Aug 2020 23:34:45
User entered 'Some interference with activity (2)'	System	06 Aug 2020 23:34:45

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-06T19:34:12', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '851af619-a89e-498b-bd6c-29710ccc58fb'	System	06 Aug 2020 23:34:45
User entered 'Some interference with activity (2)'	System	06 Aug 2020 23:34:45

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-06T19:34:17', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '851af619-a89e-498b-bd6c-29710ccc58fb'	System	06 Aug 2020 23:34:45
User entered 'None (0)'	System	06 Aug 2020 23:34:45

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-06T19:34:20', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '851af619-a89e-498b-bd6c-29710ccc58fb'	System	06 Aug 2020 23:34:45
User entered 'None (0)'	System	06 Aug 2020 23:34:45

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-06T19:34:30', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '851af619-a89e-498b-bd6c-29710ccc58fb'	System	06 Aug 2020 23:34:45
User entered 'Some interference with activity not requiring medical attention (2)'	System	06 Aug 2020 23:34:45

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-06T19:34:37', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '851af619-a89e-498b-bd6c-29710ccc58fb'	System	06 Aug 2020 23:34:45
User entered 'No (N)'	System	06 Aug 2020 23:34:45

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-06T19:34:41', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '851af619-a89e-498b-bd6c-29710ccc58fb'	System	06 Aug 2020 23:34:45
User entered '06 Aug 2020 19:34'	System	06 Aug 2020 23:34:45

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 4'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-07T19:36:50', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '3c0e8ce1-fe9f-4cce-b138-568bf53fe94a'	System	07 Aug 2020 23:37:45
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	07 Aug 2020 23:37:45

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-07T19:36:59', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '3c0e8ce1-fe9f-4cce-b138-568bf53fe94a'	System	07 Aug 2020 23:37:45
User entered 'Some interference with activity (2)'	System	07 Aug 2020 23:37:45

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-07T19:37:10', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '3c0e8ce1-fe9f-4cce-b138-568bf53fe94a'	System	07 Aug 2020 23:37:45
User entered 'Some interference with activity (2)'	System	07 Aug 2020 23:37:45

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-07T19:37:19', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '3c0e8ce1-fe9f-4cce-b138-568bf53fe94a'	System	07 Aug 2020 23:37:45
User entered 'No interference with activity (1)'	System	07 Aug 2020 23:37:45

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-07T19:37:24', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '3c0e8ce1-fe9f-4cce-b138-568bf53fe94a'	System	07 Aug 2020 23:37:45
User entered 'None (0)'	System	07 Aug 2020 23:37:45

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-07T19:37:29', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '3c0e8ce1-fe9f-4cce-b138-568bf53fe94a'	System	07 Aug 2020 23:37:45
User entered 'Some interference with activity not requiring medical attention (2)'	System	07 Aug 2020 23:37:45

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-07T19:37:37', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '3c0e8ce1-fe9f-4cce-b138-568bf53fe94a'	System	07 Aug 2020 23:37:45
User entered 'No (N)'	System	07 Aug 2020 23:37:45

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-07T19:37:42', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '3c0e8ce1-fe9f-4cce-b138-568bf53fe94a'	System	07 Aug 2020 23:37:45
User entered '07 Aug 2020 19:37'	System	07 Aug 2020 23:37:45

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 5'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-08T19:14:09', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '7eca3fc3-f841-4917-b76b-3addfe907c9f'	System	08 Aug 2020 23:14:37
User entered 'None (0)'	System	08 Aug 2020 23:14:37

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-08T19:14:13', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '7eca3fc3-f841-4917-b76b-3addfe907c9f'	System	08 Aug 2020 23:14:37
User entered 'No interference with activity (1)'	System	08 Aug 2020 23:14:37

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-08T19:14:17', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '7eca3fc3-f841-4917-b76b-3addfe907c9f'	System	08 Aug 2020 23:14:37
User entered 'No interference with activity (1)'	System	08 Aug 2020 23:14:37

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-08T19:14:20', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '7eca3fc3-f841-4917-b76b-3addfe907c9f'	System	08 Aug 2020 23:14:37
User entered 'None (0)'	System	08 Aug 2020 23:14:37

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-08T19:14:22', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '7eca3fc3-f841-4917-b76b-3addfe907c9f'	System	08 Aug 2020 23:14:37
User entered 'None (0)'	System	08 Aug 2020 23:14:37

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-08T19:14:26', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '7eca3fc3-f841-4917-b76b-3addfe907c9f'	System	08 Aug 2020 23:14:37
User entered 'None (0)'	System	08 Aug 2020 23:14:37

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-08T19:14:29', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '7eca3fc3-f841-4917-b76b-3addfe907c9f'	System	08 Aug 2020 23:14:37
User entered 'No (N)'	System	08 Aug 2020 23:14:37

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-08T19:14:32', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '7eca3fc3-f841-4917-b76b-3addfe907c9f'	System	08 Aug 2020 23:14:37
User entered '08 Aug 2020 19:14'	System	08 Aug 2020 23:14:37

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 6'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-09T19:26:38', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '828d21a1-9ccc-4f5f-bd94-cde558c4e82a'	System	09 Aug 2020 23:27:14
User entered 'None (0)'	System	09 Aug 2020 23:27:14

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-09T19:26:43', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '828d21a1-9ccc-4f5f-bd94-cde558c4e82a'	System	09 Aug 2020 23:27:14
User entered 'No interference with activity (1)'	System	09 Aug 2020 23:27:14

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-09T19:26:48', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '828d21a1-9ccc-4f5f-bd94-cde558c4e82a'	System	09 Aug 2020 23:27:14
User entered 'No interference with activity (1)'	System	09 Aug 2020 23:27:14

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-09T19:26:53', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '828d21a1-9ccc-4f5f-bd94-cde558c4e82a'	System	09 Aug 2020 23:27:14
User entered 'None (0)'	System	09 Aug 2020 23:27:14

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-09T19:26:56', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '828d21a1-9ccc-4f5f-bd94-cde558c4e82a'	System	09 Aug 2020 23:27:14
User entered 'None (0)'	System	09 Aug 2020 23:27:14

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-09T19:27:00', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '828d21a1-9ccc-4f5f-bd94-cde558c4e82a'	System	09 Aug 2020 23:27:14
User entered 'None (0)'	System	09 Aug 2020 23:27:14

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-09T19:27:05', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '828d21a1-9ccc-4f5f-bd94-cde558c4e82a'	System	09 Aug 2020 23:27:14
User entered 'No (N)'	System	09 Aug 2020 23:27:14

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-09T19:27:09', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '828d21a1-9ccc-4f5f-bd94-cde558c4e82a'	System	09 Aug 2020 23:27:14
User entered '09 Aug 2020 19:27'	System	09 Aug 2020 23:27:14

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 7'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-10T19:18:15', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'ab073ea5-b587-4399-8ba3-8f9881461e4c'	System	10 Aug 2020 23:19:27
User entered 'No interference with activity (1)'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-10T19:18:42', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'ab073ea5-b587-4399-8ba3-8f9881461e4c'	System	10 Aug 2020 23:19:27
User entered 'Some interference with activity (2)'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-10T19:18:50', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'ab073ea5-b587-4399-8ba3-8f9881461e4c'	System	10 Aug 2020 23:19:27
User entered 'No interference with activity (1)'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-10T19:19:01', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'ab073ea5-b587-4399-8ba3-8f9881461e4c'	System	10 Aug 2020 23:19:27
User entered 'No interference with activity (1)'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-10T19:19:04', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'ab073ea5-b587-4399-8ba3-8f9881461e4c'	System	10 Aug 2020 23:19:27
User entered 'None (0)'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-10T19:19:12', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'ab073ea5-b587-4399-8ba3-8f9881461e4c'	System	10 Aug 2020 23:19:27
User entered 'No interference with activity (1)'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-10T19:19:22', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'ab073ea5-b587-4399-8ba3-8f9881461e4c'	System	10 Aug 2020 23:19:27
User entered 'No (N)'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-10T19:19:25', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'ab073ea5-b587-4399-8ba3-8f9881461e4c'	System	10 Aug 2020 23:19:27
User entered '10 Aug 2020 19:19'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
Data entry locked.	System	10 Aug 2020 23:19:27
User entered 'Day 8'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:34:19

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-11T19:39:20', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'd3e20896-30cf-4eda-8508-22222c7e3316'	System	11 Aug 2020 23:39:27
User entered 'None (0)'	System	11 Aug 2020 23:39:27

US3412126

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-11T19:39:23', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'd3e20896-30cf-4eda-8508-22222c7e3316'	System	11 Aug 2020 23:39:27
User entered '11 Aug 2020 19:39'	System	11 Aug 2020 23:39:27

US3412126

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
Data entry locked.	System	09 Aug 2020 23:27:14
User entered 'Day 8'	System	09 Aug 2020 23:27:14

US3412126

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:34:19

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-11T19:39:34', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '09de7434-6352-40e8-befb-088dee7f94e3'	System	11 Aug 2020 23:39:39
User entered 'No interference with activity (1)'	System	11 Aug 2020 23:39:39

US3412126

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-11T19:39:37', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '09de7434-6352-40e8-befb-088dee7f94e3'	System	11 Aug 2020 23:39:39
User entered '11 Aug 2020 19:39'	System	11 Aug 2020 23:39:39

US3412126

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '11 Aug 2020 12:00'	System	09 Aug 2020 23:27:14

US3412126

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '12 Aug 2020 11:59'	System	09 Aug 2020 23:27:14

US3412126

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
Data entry locked.	System	10 Aug 2020 23:19:27
User entered 'Day 9'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:34:19

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54

US3412126

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54

US3412126

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
Data entry locked.	System	11 Aug 2020 23:39:39
User entered 'Day 10'	System	11 Aug 2020 23:39:39

US3412126

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:34:19

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54

US3412126

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:34:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54

US3412126

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 23:39:39

US3412126

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 23:39:39

US3412126

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
Data entry locked.	System	09 Aug 2020 23:27:14
User entered 'Day 8'	System	09 Aug 2020 23:27:14

US3412126

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:34:19

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-11T19:39:51', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '4800ddf5-7d27-4139-afe8-92c290507341'	System	11 Aug 2020 23:39:56
User entered 'No interference with activity (1)'	System	11 Aug 2020 23:39:56

US3412126

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:34:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-11T19:39:54', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '4800ddf5-7d27-4139-afe8-92c290507341'	System	11 Aug 2020 23:39:56
User entered '11 Aug 2020 19:39'	System	11 Aug 2020 23:39:56

US3412126

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '11 Aug 2020 12:00'	System	09 Aug 2020 23:27:14

US3412126

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '12 Aug 2020 11:59'	System	09 Aug 2020 23:27:14

US3412126

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
Data entry locked.	System	10 Aug 2020 23:19:27
User entered 'Day 9'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:34:19

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54

US3412126

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:34:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54

US3412126

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
Data entry locked.	System	11 Aug 2020 23:39:56
User entered 'Day 10'	System	11 Aug 2020 23:39:56

US3412126

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 17:34:19

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54

US3412126

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 17:34:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54

US3412126

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 17:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 23:39:56

US3412126

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 17:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 23:39:56

US3412126

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
Data entry locked.	System	10 Aug 2020 23:19:27
User entered 'Day 8'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:34:19

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-11T19:40:00', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '7c2ff8cc-24db-41b2-928a-4adb9673cfca'	System	11 Aug 2020 23:40:05
User entered 'None (0)'	System	11 Aug 2020 23:40:05

US3412126

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:34:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-11T19:40:03', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '7c2ff8cc-24db-41b2-928a-4adb9673cfca'	System	11 Aug 2020 23:40:05
User entered '11 Aug 2020 19:40'	System	11 Aug 2020 23:40:05

US3412126

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
Data entry locked.	System	10 Aug 2020 23:19:27
User entered 'Day 8'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 09 Jun 2021 17:34:19

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-11T19:40:08', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'c49c7b8d-93f9-4b87-9f44-a2fe97e4dc29'	System	11 Aug 2020 23:40:13
User entered 'None (0)'	System	11 Aug 2020 23:40:13

US3412126

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 09 Jun 2021 17:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 09 Jun 2021 17:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 23:19:27

US3412126

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 09 Jun 2021 17:34:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-11T19:40:11', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: 'c49c7b8d-93f9-4b87-9f44-a2fe97e4dc29'	System	11 Aug 2020 23:40:13
User entered '11 Aug 2020 19:40'	System	11 Aug 2020 23:40:13

US3412126

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
Data entry locked.	System	09 Aug 2020 23:27:14
User entered 'Day 8'	System	09 Aug 2020 23:27:14

US3412126

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-11T19:40:25', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '8299baef-d9f3-4d08-8ddb-2540336e2dd0'	System	11 Aug 2020 23:40:29
User entered 'No (N)'	System	11 Aug 2020 23:40:29

US3412126

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:34:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b033e968abc0106)', Time: '2020-08-11T19:40:27', User OID: 'PatientReportedOutcome (US3412126)', ODM File OID: '8299baef-d9f3-4d08-8ddb-2540336e2dd0'	System	11 Aug 2020 23:40:29
User entered '11 Aug 2020 19:40'	System	11 Aug 2020 23:40:29

US3412126

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '11 Aug 2020 12:00'	System	09 Aug 2020 23:27:14

US3412126

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '12 Aug 2020 11:59'	System	09 Aug 2020 23:27:14

US3412126

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
Data entry locked.	System	10 Aug 2020 23:17:47
User entered 'Day 9'	System	10 Aug 2020 23:17:47

US3412126

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54

US3412126

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:34:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54

US3412126

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 23:17:47

US3412126

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 23:17:47

US3412126

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
Data entry locked.	System	11 Aug 2020 23:39:39
User entered 'Day 10'	System	11 Aug 2020 23:39:39

US3412126

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54

US3412126

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:34:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54

US3412126

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:34:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 23:39:39

US3412126

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:34:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:54
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 23:39:39

US3412126

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:11:25

US3412126

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered '11 Aug 2020'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:11:25

US3412126

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:11:25

US3412126

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:11:25

US3412126

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 20:11:29

US3412126

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User entered 'I'	System	12 Aug 2020 20:11:29

US3412126

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User closed query 'Subject still in illness period through this date - please change to no and delete all info on this page' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:47:02
Query 'Subject still in illness period through this date - please change to no and delete all info on this page' answered with 'subject was still in illness phase and this visit was not indicated' (Site from CRA).	Steven Anderson (b) (4) (b) (4)	18 Nov 2020 13:50:42
User entered 'No (N)' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	18 Nov 2020 13:50:20
User opened query 'Subject still in illness period through this date - please change to no and delete all info on this page' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 18:58:48
User entered 'Yes (Y)'		18 Aug 2020 23:47:57

US3412126

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:19

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered empty; reason for change Data Entry Error	(b) (4)	18 Nov 2020 13:50:20
User entered '18 Aug 2020'	Steven Anderson (b) (4)	18 Aug 2020 23:47:57
	(b) (4), (b) (6)	

US3412126

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered empty; reason for change Data Entry Error	(b) (4)	18 Nov 2020 13:50:20
User entered 'Contact Made (CONTACT MADE)'	Steven Anderson (b) (4)	18 Aug 2020 23:47:57
	(b) (4), (b) (6)	

US3412126

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 23:47:57

US3412126

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 23:48:01

US3412126

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:11
User entered '1'	System	18 Aug 2020 23:48:01

US3412126

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:25
User signature succeeded.	Richard Powell (b) (4)	19 Feb 2021 03:55:44
User closed query 'Per CDM: Please complete Visit date and exposure form under Visit 2 folder. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:40:24
Query 'Per CDM: Please complete Visit date and exposure form under Visit 2 folder. Thank you' answered with 'this form has been completed' (Site from DM).	Steven Anderson (b) (4) (b) (4)	18 Feb 2021 14:44:39
User opened query 'Per CDM: Please complete Visit date and exposure form under Visit 2 folder. Thank you' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 12:33:48
User entered 'Yes (Y)'		27 Aug 2020 16:17:55

US3412126

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:25
User signature succeeded.	Richard Powell (b) (4)	19 Feb 2021 03:55:44
User entered '27 Aug 2020'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 16:17:55

US3412126

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:25
User signature succeeded.	Richard Powell (b) (4)	19 Feb 2021 03:55:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 16:17:55

US3412126

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:25
User signature succeeded.	Richard Powell (b) (4)	19 Feb 2021 03:55:44
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 16:17:55

US3412126

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:25
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:40
User closed query 'please confirm subject not continuing? If so, please complete end of study' (Site from CRA).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:02:22
Query 'please confirm subject not continuing? If so, please complete end of study' answered with 'PARTICIPANT IS CONTINUING BUT DUE TO AE'S THAT STARTED ON THEY ARE NOW GETTING SAFETY SICK CALL VISITS.' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 20:10:06
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 20:07:23
User opened query 'please confirm subject not continuing? If so, please complete end of study' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 19:41:37
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	18 Nov 2020 13:56:15

US3412126

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:25
User entered '1'	System	20 Nov 2020 20:07:23
User entered empty.	System	18 Nov 2020 13:56:15

US3412126

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
	(b) (4)	
User entered 'No (N)'	Steven Anderson (b) (4)	10 Feb 2021 16:44:57
	(b) (4)	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	10 Feb 2021 16:44:57
	(b) (4)	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	10 Feb 2021 16:44:57
	(b) (4)	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:19

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	10 Feb 2021 16:44:57

US3412126

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:19

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Steven Anderson (b) (4)	10 Feb 2021 16:45:04
	(b) (4)	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
	(b) (4)	
User entered 'No (N)'	Steven Anderson (b) (4)	10 Feb 2021 16:45:04
	(b) (4)	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	10 Feb 2021 16:45:04
	(b) (4)	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	10 Feb 2021 16:45:04
	(b) (4)	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 16:45:04

US3412126

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	10 Feb 2021 16:45:04
	(b) (4)	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:19

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	10 Feb 2021 16:45:04
	(b) (4)	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:19

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	10 Feb 2021 16:45:04
	(b) (4)	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	10 Feb 2021 16:45:04
	(b) (4)	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 16:45:04

US3412126

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	10 Feb 2021 16:45:04
	(b) (4)	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 16:45:04

US3412126

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	10 Feb 2021 16:45:04
	(b) (4)	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 16:45:04

US3412126

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	10 Feb 2021 16:45:04
	(b) (4)	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 16:45:04

US3412126

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:19

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Steven Anderson (b) (4) (b) (4)	10 Feb 2021 16:45:04

US3412126

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
	(b) (4)	
User entered 'No (N)'	Steven Anderson (b) (4)	10 Feb 2021 16:45:04
	(b) (4)	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	10 Feb 2021 16:45:04
	(b) (4)	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	10 Feb 2021 16:45:04
	(b) (4)	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 16:45:04

US3412126

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	10 Feb 2021 16:45:04
	(b) (4)	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:19

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	10 Feb 2021 16:45:04
	(b) (4)	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:19

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	10 Feb 2021 16:45:04
	(b) (4)	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	10 Feb 2021 16:45:04
	(b) (4)	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 16:45:04

US3412126

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	10 Feb 2021 16:45:04
	(b) (4)	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 16:45:04

US3412126

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	10 Feb 2021 16:45:04
	(b) (4)	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 16:45:04

US3412126

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	10 Feb 2021 16:45:04
	(b) (4)	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 16:45:04

US3412126

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
	(b) (4)	
User entered 'No (N)'	Steven Anderson (b) (4)	10 Feb 2021 16:45:11
	(b) (4)	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:19

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	10 Feb 2021 16:45:11
	(b) (4)	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
	(b) (4)	
User entered 'No (N)'	Steven Anderson (b) (4)	10 Feb 2021 16:45:17
	(b) (4)	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:19

If No, reason not given

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
	(b) (4)	
User closed query 'Was study treatment given? is No, System however If No, reason not given is not provided. Please review and reconcile.' (Site from System).		10 Feb 2021 16:45:27
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)' reason for change: Data Entry Error	Steven Anderson (b) (4)	10 Feb 2021 16:45:27
	(b) (4)	
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	10 Feb 2021 16:45:17
User entered empty.	Steven Anderson (b) (4)	10 Feb 2021 16:45:17
	(b) (4)	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	10 Feb 2021 16:45:17
	(b) (4)	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:19

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 16:45:17

US3412126

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:19

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	10 Feb 2021 16:45:17
	(b) (4)	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:19

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	10 Feb 2021 16:45:17
	(b) (4)	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:19

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 16:45:17

US3412126

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:19

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	10 Feb 2021 16:45:17
	(b) (4)	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:19

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 16:45:17

US3412126

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:19

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 16:45:17

US3412126

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
	(b) (4)	
User entered 'No (N)'	Steven Anderson (b) (4)	10 Feb 2021 16:45:32
	(b) (4)	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:19

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	10 Feb 2021 16:45:32
	(b) (4)	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	10 Feb 2021 16:45:32
	(b) (4)	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 16:45:32

US3412126

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:34:19

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	10 Feb 2021 16:45:38
	(b) (4)	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:34:19

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Steven Anderson (b) (4)	10 Feb 2021 16:45:38

US3412126

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:34:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
	(b) (4)	
User entered 'No (N)'	Steven Anderson (b) (4)	10 Feb 2021 16:45:38
	(b) (4)	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:34:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	10 Feb 2021 16:45:38
	(b) (4)	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:34:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 16:45:38

US3412126

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:34:19

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Steven Anderson (b) (4)	10 Feb 2021 16:45:38

US3412126

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:34:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
	(b) (4)	
User entered 'No (N)'	Steven Anderson (b) (4)	10 Feb 2021 16:45:38
	(b) (4)	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:34:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	10 Feb 2021 16:45:38
	(b) (4)	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:34:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 16:45:38

US3412126

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
Signature has been broken.	Steven Anderson (b) (4)	05 Apr 2021 18:45:59
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Steven Anderson (b) (4)	05 Apr 2021 18:45:59
	(b) (4)	
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:34
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Steven Anderson (b) (4)	10 Feb 2021 16:46:26
	(b) (4)	
User entered 'Yes (Y)'	Steven Anderson (b) (4)	10 Feb 2021 16:46:19
	(b) (4)	

US3412126

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 18:45:59
User entered empty.	System	10 Feb 2021 16:46:26
User entered '1'	System	10 Feb 2021 16:46:19

US3412126

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered 'No (N)'	Steven Anderson (b) (4)	05 Apr 2021 18:46:07
	(b) (4)	

US3412126

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	05 Apr 2021 18:46:07
	(b) (4)	

US3412126

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	05 Apr 2021 18:46:07
	(b) (4)	

US3412126

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered 'Subject was in the middle of an SAE and due to the illness site was trying to get medical records subjects SAE did not resolve completely until 20-Jan-2021' reason for change: Data Entry Error	Steven Anderson (b) (4)	05 Apr 2021 18:47:51
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	05 Apr 2021 18:46:07
	(b) (4)	

US3412126

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered 'Yes (Y)'	Steven Anderson (b) (4)	05 Apr 2021 18:46:11
	(b) (4)	

US3412126

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 18:46:11

US3412126

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered 'No (N)'	Steven Anderson (b) (4)	05 Apr 2021 18:46:44
	(b) (4)	

US3412126

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	05 Apr 2021 18:46:44
	(b) (4)	

US3412126

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	05 Apr 2021 18:46:44
	(b) (4)	

US3412126

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered 'Subject was in the middle of an SAE and due to the illness site was trying to get medical records subjects SAE did not resolve completely until 20-Jan-2021' reason for change: Data Entry Error	Steven Anderson (b) (4)	05 Apr 2021 18:47:35
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	05 Apr 2021 18:46:44
	(b) (4)	

US3412126

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered 'Yes (Y)'	Steven Anderson (b) (4)	05 Apr 2021 18:47:40
	(b) (4)	

US3412126

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 18:47:40

US3412126

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered 'No (N)'	Steven Anderson (b) (4)	05 Apr 2021 18:48:00
	(b) (4)	

US3412126

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	05 Apr 2021 18:48:00
	(b) (4)	

US3412126

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	05 Apr 2021 18:48:00
	(b) (4)	

US3412126

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered 'Subject was in the middle of an SAE and due to the illness site was trying to get medical records subjects SAE did not resolve completely until 20-Jan-2021'	Steven Anderson (b) (4)	05 Apr 2021 18:48:00
	(b) (4)	

US3412126

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered 'Yes (Y)'	Steven Anderson (b) (4)	05 Apr 2021 18:48:04
	(b) (4)	

US3412126

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 18:48:04

US3412126

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered 'No (N)'	Steven Anderson (b) (4)	05 Apr 2021 18:48:10
	(b) (4)	

US3412126

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	05 Apr 2021 18:48:10
	(b) (4)	

US3412126

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	05 Apr 2021 18:48:10
	(b) (4)	

US3412126

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:19

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	05 Apr 2021 18:48:10

US3412126

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered 'No (N)'	Steven Anderson (b) (4)	05 Apr 2021 18:48:14
	(b) (4)	

US3412126

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	05 Apr 2021 18:48:14
	(b) (4)	

US3412126

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	05 Apr 2021 18:48:14
	(b) (4)	

US3412126

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 18:48:14

US3412126

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	05 Apr 2021 18:48:14
	(b) (4)	

US3412126

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	05 Apr 2021 18:48:14
	(b) (4)	

US3412126

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	05 Apr 2021 18:48:14
	(b) (4)	

US3412126

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	05 Apr 2021 18:48:14
	(b) (4)	

US3412126

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 18:48:14

US3412126

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	05 Apr 2021 18:48:14
	(b) (4)	

US3412126

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 18:48:14

US3412126

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	05 Apr 2021 18:48:14
	(b) (4)	

US3412126

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 18:48:14

US3412126

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	05 Apr 2021 18:48:14
	(b) (4)	

US3412126

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 18:48:14

US3412126

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered 'No (N)'	Steven Anderson (b) (4)	05 Apr 2021 18:48:19
	(b) (4)	

US3412126

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:19

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	05 Apr 2021 18:48:19
	(b) (4)	

US3412126

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered 'No (N)'	Steven Anderson (b) (4)	05 Apr 2021 18:48:23
	(b) (4)	

US3412126

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:19

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	05 Apr 2021 18:48:23
	(b) (4)	

US3412126

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	05 Apr 2021 18:48:23
	(b) (4)	

US3412126

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 18:48:23

US3412126

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered 'Yes (Y)'	Steven Anderson (b) (4)	05 Apr 2021 18:48:27
	(b) (4)	

US3412126

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 18:48:27

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 64'	System	04 Aug 2020 20:23:53

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32
Data entry locked.	System	04 Aug 2020 20:23:53
User entered '04 Oct 2020 00:01'	System	04 Aug 2020 20:23:53

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32
Data entry locked.	System	04 Aug 2020 20:23:53
User entered '08 Oct 2020 23:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 71'	System	04 Aug 2020 20:23:53

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Please 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)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32
Data entry locked.	System	04 Aug 2020 20:23:53
User entered '11 Oct 2020 00:01'	System	04 Aug 2020 20:23:53

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32
Data entry locked.	System	04 Aug 2020 20:23:53
User entered '15 Oct 2020 23:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 78'	System	04 Aug 2020 20:23:53

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32
Data entry locked.	System	04 Aug 2020 20:23:53
User entered '18 Oct 2020 00:01'	System	04 Aug 2020 20:23:53

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32
Data entry locked.	System	04 Aug 2020 20:23:53
User entered '22 Oct 2020 23:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 92'	System	04 Aug 2020 20:23:53

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32
Data entry locked.	System	04 Aug 2020 20:23:53
User entered '01 Nov 2020 00:01'	System	04 Aug 2020 20:23:53

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32
Data entry locked.	System	04 Aug 2020 20:23:53
User entered '05 Nov 2020 23:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 99'	System	04 Aug 2020 20:23:53

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32
Data entry locked.	System	04 Aug 2020 20:23:53
User entered '08 Nov 2020 00:01'	System	04 Aug 2020 20:23:53

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32
Data entry locked.	System	04 Aug 2020 20:23:53
User entered '12 Nov 2020 23:59'	System	04 Aug 2020 20:23:53

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32
Data entry locked.	System	04 Aug 2020 20:23:53
User entered 'Day 106'	System	04 Aug 2020 20:23:53

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[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)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

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Folder: Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32

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Folder: Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32
Data entry locked.	System	04 Aug 2020 20:23:53
User entered '15 Nov 2020 00:01'	System	04 Aug 2020 20:23:53

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:04
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:50:32
Data entry locked.	System	04 Aug 2020 20:23:53
User entered '19 Nov 2020 23:59'	System	04 Aug 2020 20:23:53

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Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 12:50:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 12:50:32

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 12:50:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 12:50:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 12:50:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 12:50:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 12:50:32

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Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 12:50:32

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 12:50:32

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Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:34:19

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 12:50:32

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Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 12:50:32

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 12:50:32

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Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 12:50:32

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 12:50:32

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 12:50:32

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Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 12:50:32

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 12:50:32

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 12:50:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 12:50:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 12:50:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 12:50:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 12:50:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 12:50:32

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 12:50:32

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Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 12:50:32

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 12:50:32

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 12:50:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 12:50:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 12:50:32

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 12:50:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 12:50:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 12:50:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 12:50:32

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Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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

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US3412126

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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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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

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US3412126

Folder: New Safety Follow Up Diary (1)

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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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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Please 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)
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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Please 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)
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US3412126

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
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US3412126

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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Please 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)
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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US3412126

Folder: New Safety Follow Up Diary (1)

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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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
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US3412126

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US3412126

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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Please 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)
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US3412126

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3412126

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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Please 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)
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US3412126

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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Folder: New Safety Follow Up Diary (1)

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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Please 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)
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US3412126

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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Please 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)
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US3412126

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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

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US3412126

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

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

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US3412126

Folder: New Safety Follow Up Diary (1)

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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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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

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[Date and time of submission](#)

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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Please 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)
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US3412126

Folder: New Safety Follow Up Diary (1)

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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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
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DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

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DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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

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DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

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

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Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

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US3412126

Folder: New Safety Follow Up Diary (1)

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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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Please 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)
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US3412126

Folder: New Safety Follow Up Diary (1)

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Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

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US3412126

Folder: New Safety Follow Up Diary (1)

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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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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

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US3412126

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
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US3412126

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

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Folder: New Safety Follow Up Diary (1)

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Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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Please 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)
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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US3412126

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
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US3412126

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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Please 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)
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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

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DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

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DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

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

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Folder: New Safety Follow Up Diary (1)

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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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

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Folder: New Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

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Folder: New Safety Follow Up Diary (1)

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

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Folder: New Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

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Folder: New Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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[Congestion](#)

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[Runny nose](#)

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US3412126

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[Nausea](#)

Audit	User	Time (GMT)
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US3412126

Folder: New Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
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US3412126

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[Patient Cloud Open Date & Time](#)

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DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[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)
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US3412126

Folder: New Safety Follow Up Diary (1)

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Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

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US3412126

Folder: New Safety Follow Up Diary (1)

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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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
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US3412126

Folder: New Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
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US3412126

Folder: New Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

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Folder: New Safety Follow Up Diary (1)

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[Body aches](#)

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US3412126

Folder: New Safety Follow Up Diary (1)

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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

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US3412126

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
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US3412126

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
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DataPoint Inactivated.	System	05 Apr 2021 18:25:54

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Folder: New Safety Follow Up Diary (1)

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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Please 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)
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US3412126

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
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US3412126

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:34:19

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Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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US3412126

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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Please 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)
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US3412126

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Please 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)
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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

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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

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DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
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US3412126

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

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Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
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US3412126

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
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US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
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US3412126

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Have you been exposed to someone with 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Shortness of breath](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Muscle aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Body aches](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of taste](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[New loss of smell](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Sore throat](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Congestion](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Runny nose](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

Please 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)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Date and time of submission](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 12:50:32

US3412126

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	05 Apr 2021 18:45:24
DataPoint Inactivated.	System	05 Apr 2021 18:25:54
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:50:32
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 12:50:32

US3412126

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered 'No (N)'	Steven Anderson (b) (4)	05 Apr 2021 18:48:45
	(b) (4)	

US3412126

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	05 Apr 2021 18:48:45
	(b) (4)	

US3412126

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	05 Apr 2021 18:48:45
	(b) (4)	

US3412126

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered 'Subject was in the middle of an SAE and due to the illness site was trying to get medical records subjects SAE did not resolve completely until 20-Jan-2021'	Steven Anderson (b) (4)	05 Apr 2021 18:48:45
	(b) (4)	

US3412126

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered 'Yes (Y)'	Steven Anderson (b) (4)	05 Apr 2021 18:48:49
	(b) (4)	

US3412126

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 18:48:49

US3412126

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered 'No (N)'	Steven Anderson (b) (4)	05 Apr 2021 18:48:58
	(b) (4)	

US3412126

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	05 Apr 2021 18:48:58
	(b) (4)	

US3412126

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	05 Apr 2021 18:48:58
	(b) (4)	

US3412126

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered 'Subject was in the middle of an SAE and due to the illness site was trying to get medical records subjects SAE did not resolve completely until 20-Jan-2021'	Steven Anderson (b) (4)	05 Apr 2021 18:48:58
	(b) (4)	

US3412126

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered 'Yes (Y)'	Steven Anderson (b) (4)	05 Apr 2021 18:49:02
	(b) (4)	

US3412126

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 18:49:02

US3412126

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered 'No (N)'	Steven Anderson (b) (4)	05 Apr 2021 18:49:11
	(b) (4)	

US3412126

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	05 Apr 2021 18:49:11
	(b) (4)	

US3412126

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	05 Apr 2021 18:49:11
	(b) (4)	

US3412126

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered 'Subject was in the middle of an SAE and due to the illness site was trying to get medical records subjects SAE did not resolve completely until 20-Jan-2021'	Steven Anderson (b) (4)	05 Apr 2021 18:49:11
	(b) (4)	

US3412126

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered 'Yes (Y)'	Steven Anderson (b) (4)	05 Apr 2021 18:49:15
	(b) (4)	

US3412126

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 18:49:15

US3412126

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered 'No (N)'	Steven Anderson (b) (4)	05 Apr 2021 18:49:24
	(b) (4)	

US3412126

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	05 Apr 2021 18:49:24
	(b) (4)	

US3412126

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	05 Apr 2021 18:49:24
	(b) (4)	

US3412126

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered 'Subject was in the middle of an SAE and due to the illness site was trying to get medical records subjects SAE did not resolve completely until 20-Jan-2021'	Steven Anderson (b) (4)	05 Apr 2021 18:49:24
	(b) (4)	

US3412126

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered 'Yes (Y)'	Steven Anderson (b) (4)	05 Apr 2021 18:49:30
	(b) (4)	

US3412126

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 18:49:30

US3412126

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered 'No (N)'	Steven Anderson (b) (4)	08 Apr 2021 18:25:47
	(b) (4)	

US3412126

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	08 Apr 2021 18:25:47
	(b) (4)	

US3412126

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	08 Apr 2021 18:25:47
	(b) (4)	

US3412126

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:19

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	08 Apr 2021 18:25:47

US3412126

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered 'No (N)'	Steven Anderson (b) (4)	08 Apr 2021 18:25:55
	(b) (4)	

US3412126

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	08 Apr 2021 18:25:55
	(b) (4)	

US3412126

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	08 Apr 2021 18:25:55
	(b) (4)	

US3412126

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 18:25:55

US3412126

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	08 Apr 2021 18:25:55
	(b) (4)	

US3412126

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	08 Apr 2021 18:25:55
	(b) (4)	

US3412126

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	08 Apr 2021 18:25:55
	(b) (4)	

US3412126

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	08 Apr 2021 18:25:55
	(b) (4)	

US3412126

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 18:25:55

US3412126

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	08 Apr 2021 18:25:55
	(b) (4)	

US3412126

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 18:25:55

US3412126

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	08 Apr 2021 18:25:55
	(b) (4)	

US3412126

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 18:25:55

US3412126

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	08 Apr 2021 18:25:55
	(b) (4)	

US3412126

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 18:25:55

US3412126

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered 'No (N)'	Steven Anderson (b) (4)	08 Apr 2021 18:26:03
	(b) (4)	

US3412126

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:19

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	08 Apr 2021 18:26:03
	(b) (4)	

US3412126

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered 'No (N)'	Steven Anderson (b) (4)	08 Apr 2021 18:26:09
	(b) (4)	

US3412126

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:19

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	08 Apr 2021 18:26:09
	(b) (4)	

US3412126

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	08 Apr 2021 18:26:09
	(b) (4)	

US3412126

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 18:26:09

US3412126

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered 'Yes (Y)'	Steven Anderson (b) (4)	08 Apr 2021 18:25:40
	(b) (4)	

US3412126

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 18:25:40

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:34:19

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:43
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User closed query 'please add and complete illness visit folder (convalescent visit in add event)' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 00:05:23
Query 'please add and complete illness visit folder (convalescent visit in add event)' answered with 'illness visit added.' (Site from CRA).	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 15:03:40
User opened query 'please add and complete illness visit folder (convalescent visit in add event)' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 19:00:05
DataPoint Verified.	(b) (4)	04 Nov 2020 18:59:18
User entered '12 Aug 2020'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:04:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:34:19

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:43
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:59:18
User entered '16:45'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:04:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:34:19

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:43
User entered '12 Aug 2020 16:45'	System	06 Oct 2020 19:04:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:34:19

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:43
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:59:18
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:04:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:34:19

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:43
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:59:18
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:04:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:34:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User closed query 'Symptom log begins with symptom onset - this is 5 Aug 2020 per source? Please review and update to include 5-11 Aug 2020' (Site from CRA).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 01:59:29
Query 'Symptom log begins with symptom onset - this is 5 Aug 2020 per source? Please review and update to include 5-11 Aug 2020' answered with 'UPDATED SYSTEM LOG FOR DAYS OF SYMPTON ONSET' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:17:59
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:13:25
User opened query 'Symptom log begins with symptom onset - this is 5 Aug 2020 per source? Please review and update to include 5-11 Aug 2020' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 18:43:15
User closed query 'Please consolidate all days related to this convalescent period into this symptom Log by adding additional days here. ' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 18:04:23
Query 'Please consolidate all days related to this convalescent period into this symptom Log by adding additional days here. ' answered with 'updating ' (Site from CRA).	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:18:21
User opened query 'Please consolidate all days related to this convalescent period into this symptom Log by adding additional days here. ' (Site from CRA).	(b) (4), (b) (6)	07 Oct 2020 17:35:21
User entered 'Day 1 (Day 1)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:07:27

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:34:19

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:04
User entered '12 Aug 2020'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:07:27

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:34:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered '0'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:07:27

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:34:19

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User closed query 'Per CDM: It appears that O2 Saturation for Day 8 was not provided. If not collected, please consider recording as 'Not Done'. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Jan 2021 09:38:57
Query 'Per CDM: It appears that O2 Saturation for Day 8 was not provided. If not collected, please consider recording as 'Not Done'. Thank you.' answered with 'O2 SATURATION FOR DAY 8 WAS NOT DONE. UPDATED FIELD' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	11 Jan 2021 18:56:21
DataPoint Un-verified.	Melissa Fuson (b) (4) (b) (4)	11 Jan 2021 18:55:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Melissa Fuson (b) (4) (b) (4)	11 Jan 2021 18:55:38
User opened query 'Per CDM: It appears that O2 Saturation for Day 8 was not provided. If not collected, please consider recording as 'Not Done'. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 10:32:14
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:47:11
User entered empty.	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:07:27

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:34:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User entered '%'	System	11 Jan 2021 18:55:38
User entered empty.	System	06 Oct 2020 19:07:27

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:34:19

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:08
User entered '99.2' F	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:07:27

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:15
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:07:27

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:48:34
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:07:27

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:34:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:48:36
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:07:27

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:34:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:48:38
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:07:27

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:48:40
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:07:27

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:34:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:48:42
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:07:27

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:34:19

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:48:44
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:07:27

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:48:50
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:07:27

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:34:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 02:00:13
User closed query 'please confirm - source only indicates lack of appetite' (Site from CRA).	(b) (4)	24 Nov 2020 02:00:10
Query 'please confirm - source only indicates lack of appetite' answered with 'UPDATED' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:19:57
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:19:45
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 18:50:54
DataPoint Verified.	(b) (4)	04 Nov 2020 18:50:42
User opened query 'please confirm - source only indicates lack of appetite' (Site from CRA).	(b) (4)	04 Nov 2020 18:49:33
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:07:27

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:34:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:49:39
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:07:27

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:34:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:49:40
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:07:27

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:34:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:49:42
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:07:27

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:49:44
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:07:27

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:49:48
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:07:27

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:49:47
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:07:27

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:34:19

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:49:52
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:07:27

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:34:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4) (b) (4)	16 Apr 2021 14:22:28
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:13:25
User entered 'Day 2 (Day 2)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:34:19

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:49:59
User entered '13 Aug 2020'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:34:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:02
User entered '0'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:34:19

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:08
User entered '99'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:34:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User entered '%'	System	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:34:19

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:11
User entered '97.5' F	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:13
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:15
User entered 'Mild (Mild)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:34:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:22
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:34:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:26
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:28
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:34:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:30
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:34:19

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:31
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:33
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:34:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:35
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:34:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:36
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:34:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:34:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:34:19

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:34:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4) (b) (4)	16 Apr 2021 14:22:28
User entered 'Day 10 (Day 10)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:13:25
User entered 'Day 3 (Day 3)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:34:19

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered '14 Aug 2020'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:34:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered '0'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:34:19

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered '97'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:34:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User entered '%'	System	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:34:19

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered '98.2' F	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'Mild (Mild)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:34:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:34:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:34:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:34:19

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:34:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:34:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:34:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:34:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:34:19

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:34:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4) (b) (4)	16 Apr 2021 14:22:28
User entered 'Day 11 (Day 11)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:13:25
User entered 'Day 4 (Day 4)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:34:19

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered '15 Aug 2020'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:34:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered '0'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:34:19

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered '98' reason for change: Data Entry Error	Jacob sekinger (b) (4)	07 Oct 2020 21:39:25
User entered empty.	(b) (4) Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:34:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User entered '%'	System	07 Oct 2020 21:39:25
User entered empty.	System	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:34:19

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered '98' F reason for change: Data Entry Error	Jacob sekinger (b) (4)	07 Oct 2020 21:39:25
User entered empty.	(b) (4) Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:34:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:34:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:34:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:34:19

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:34:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:34:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:34:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:34:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:34:19

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:34:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4) (b) (4)	16 Apr 2021 14:22:28
User entered 'Day 12 (Day 12)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:13:25
User entered 'Day 5 (Day 5)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:34:19

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered '16 Aug 2020'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:34:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered '0'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:34:19

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered '97' reason for change: Data Entry Error	Jacob sekinger (b) (4)	07 Oct 2020 21:39:25
User entered empty.	(b) (4) Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:34:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User entered '%'	System	07 Oct 2020 21:39:25
User entered empty.	System	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:34:19

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered '98.1' F reason for change: Data Entry Error	Jacob sekinger (b) (4)	07 Oct 2020 21:39:25
User entered empty.	(b) (4) Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:34:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:34:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:34:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:34:19

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:34:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:34:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:34:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:34:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:34:19

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:34:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4) (b) (4)	16 Apr 2021 14:22:28
User entered 'Day 13 (Day 13)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:13:25
User entered 'Day 6 (Day 6)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:34:19

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered '17 Aug 2020'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:34:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered '0'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:34:19

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered '97' reason for change: Data Entry Error	Jacob sekinger (b) (4)	07 Oct 2020 21:39:25
User entered empty.	(b) (4) Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:34:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User entered '%'	System	07 Oct 2020 21:39:25
User entered empty.	System	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:34:19

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered '98.2' F reason for change: Data Entry Error	Jacob sekinger (b) (4)	07 Oct 2020 21:39:25
User entered empty.	(b) (4) Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:34:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:34:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:34:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:34:19

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:34:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:34:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:34:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:34:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:34:19

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:37:35

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:34:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered 'Day 14 (Day 14)' reason for change: Data Entry Error	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:13:25
User entered 'Day 7 (Day 7)'	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:34:19

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered '18 Aug 2020'	Melissa Fuson (b) (4)	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:34:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered '0'	Melissa Fuson (b) (4)	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:34:19

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered '96'	Melissa Fuson (b) (4)	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:34:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User entered '%'	System	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:34:19

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered '98.2' F	Melissa Fuson (b) (4)	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Melissa Fuson (b) (4)	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Melissa Fuson (b) (4)	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:34:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Melissa Fuson (b) (4)	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:34:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Melissa Fuson (b) (4)	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Melissa Fuson (b) (4)	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:34:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Melissa Fuson (b) (4)	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:34:19

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Melissa Fuson (b) (4)	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Melissa Fuson (b) (4)	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:34:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Melissa Fuson (b) (4)	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:34:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Melissa Fuson (b) (4)	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:34:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Melissa Fuson (b) (4)	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:34:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Melissa Fuson (b) (4)	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Melissa Fuson (b) (4)	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Melissa Fuson (b) (4)	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Melissa Fuson (b) (4)	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:34:19

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:50:42
User entered 'None (None)'	Melissa Fuson (b) (4)	26 Oct 2020 17:57:36
DataPoint activated with code reason code Data required.	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:56:13
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:30:44

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:34:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered 'Day 1 (Day 1)'	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:14:14

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Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:34:19

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered '05 Aug 2020'	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:34:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered '1'	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:34:19

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:34:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User entered empty.	System	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:34:19

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:34:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:34:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:34:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:34:19

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:34:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:34:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:34:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:34:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:34:19

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:14:14

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:34:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered 'Day 2 (Day 2)'	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:14:37

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:34:19

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered '06 Aug 2020'	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:14:37
	(b) (4)	

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Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:34:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered '1'	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:14:37

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:34:19

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:14:37

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:34:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User entered empty.	System	23 Nov 2020 14:14:37

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:34:19

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:14:37

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:14:37

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:14:37

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:34:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:14:37

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:34:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:14:37

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:14:37

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:34:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:14:37

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:34:19

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:14:37

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:14:37

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:34:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:14:37

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:34:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:14:37

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:34:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:14:37

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:34:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:14:37

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:14:37

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:14:37

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:14:37

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:34:19

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:14:37
	(b) (4)	

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:34:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered 'Day 3 (Day 3)'	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:34:19

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered '07 Aug 2020'	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:34:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered 'I'	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:34:19

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:34:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User entered empty.	System	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:34:19

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:34:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:34:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:34:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:34:19

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:34:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:34:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:34:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:34:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:34:19

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:15:02

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:34:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered 'Day 4 (Day 4)'	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:34:19

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered '08 Aug 2020'	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:34:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered 'I'	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:34:19

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:34:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User entered empty.	System	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:34:19

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:34:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:34:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:34:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:34:19

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:34:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:34:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:34:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:34:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:15:25

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:34:19

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:15:25

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Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:34:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered 'Day 5 (Day 5)'	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:34:19

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered '09 Aug 2020'	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:34:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered '1'	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:34:19

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:34:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User entered empty.	System	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:34:19

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:34:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:34:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:34:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:34:19

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:34:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:34:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:34:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:34:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:34:19

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:03

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:34:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered 'Day 6 (Day 6)'	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:34:19

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered '10 Aug 2020'	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:34:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered '1'	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:34:19

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:34:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User entered empty.	System	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:34:19

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:34:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:34:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:34:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:34:19

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:34:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:34:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:34:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:34:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:34:19

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:22

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:34:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered 'Day 7 (Day 7)'	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:34:19

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered '11 Aug 2020'	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:34:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered '1'	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:34:19

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:34:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User entered empty.	System	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:34:19

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:34:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:34:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:34:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:34:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:34:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:58

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Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:34:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:34:19

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:34:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:34:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:34:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:34:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:34:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:34:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:34:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:34:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:34:19

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:52
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Melissa Fuson (b) (4)	23 Nov 2020 14:16:58

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:34:19

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:59
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:04:55
User entered '12 Aug 2020'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:08:38

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:34:19

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:59
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:04:55
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:08:38

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:34:19

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:59
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:04:55
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:08:38

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:34:19

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:59
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
Query 'Per GCL Lab Reconciliation requery: Swab: Per below responses, it indicates swab sample was shipped; however, per PPD portal it indicates swab sample for 12-AUG-2020 is not yet received. Kindly consider to review the shipment if it is shipped or not if shipped, please provide the Accession, tracking number, shipped date for this sample, else clarify. ' canceled (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 04:48:04
User opened query 'Per GCL Lab Reconciliation requery: Swab: Per below responses, it indicates swab sample was shipped; however, per PPD portal it indicates swab sample for 12-AUG-2020 is not yet received. Kindly consider to review the shipment if it is shipped or not, if shipped, please provide the Accession, tracking number, shipped date for this sample, else clarify. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 12:16:43
User closed query 'Per GCL Lab Reconciliation requery: Swab: Thank you for your response, however, please provide tracking details in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 07:33:23
Query 'Per GCL Lab Reconciliation requery: Swab: Thank you for your response, however, please provide tracking details in query response for tracking purpose.' answered with 'SWAB TRACK 9108090177764 - BLOOD TRACK - 906907892369' (Site from DM).	Melissa Fuson (b) (4)	11 Jan 2021 18:53:50
User opened query 'Per GCL Lab Reconciliation requery: Swab: Thank you for your response, however, please provide tracking details in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 09:05:51
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 12-AUG-2020 is recorded under Covid-19 Assessment visit in EDC, however, swab sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 07:26:20

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:34:19

[Date of Test](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 12-AUG-2020 is recorded under Covid-19 Assessment visit in EDC, however, swab sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'PLEASE SEE ACCESSION NUMBER 1F62205' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 14:35:57
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 12-AUG-2020 is recorded under Covid-19 Assessment visit in EDC, however, swab sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 06:35:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:04:55
User entered '12 Aug 2020'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:08:38

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:34:19

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:59
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:04:55
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:08:38

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:34:19

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:59
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:04:55
User entered empty.	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:08:38

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:34:19

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:59
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:04:55
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:08:38

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:34:19

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:59
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:04:55
User entered empty.	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:08:38

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:34:19

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:59
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:04:55
User entered empty.	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:08:38

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:34:19

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:59
User entered '0'	System	06 Oct 2020 19:08:38

US3412126

Folder: Covid-19 Assessment 12 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:34:19

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:44:13
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:02:55
User closed query 'please delete data from all COVID assessments after current folder and change response to NO. Only 1 COVID folder/COVID event' (Site from CRA).		04 Nov 2020 18:02:50
Query 'please delete data from all COVID assessments after current folder and change response to NO. Only 1 COVID folder/COVID event' answered with 'UPDATED PER NEW COVID-19 ASSESSMENT' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 18:10:30
User entered 'No (N)' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	07 Oct 2020 21:42:36
User opened query 'please delete data from all COVID assessments after current folder and change response to NO. Only 1 COVID folder/COVID event' (Site from CRA).	(b) (4), (b) (6)	07 Oct 2020 17:36:41
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:09:50

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:34:19

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:46:08

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:34:19

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Steven Anderson (b) (4)	08 Apr 2021 18:08:12
	(b) (4)	
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	06 Nov 2020 14:46:08
	(b) (4)	

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:34:19

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User closed query 'Per GCL Lab Reconciliation: Saliva: per response, the sample is still not received by PPD central lab, please reverify and update.Thanks' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 09:55:38
Query 'Per GCL Lab Reconciliation: Saliva: per response, the sample is still not received by PPD central lab, please reverify and update.Thanks' answered with 'no saliva was collected by the subject' (Site from DM).	Steven Anderson (b) (4) (b) (4)	08 Apr 2021 18:08:22
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4) (b) (4)	08 Apr 2021 18:08:12
User opened query 'Per GCL Lab Reconciliation: Saliva: per response, the sample is still not received by PPD central lab, please reverify and update.Thanks' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 09:15:37
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14,16,18AUG2020 is recorded under Illness Visit Day 3,5,7 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).		19 Jan 2021 07:32:51
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14,16,18AUG2020 is recorded under Illness Visit Day 3,5,7 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'SEE ACCESSION NUMBER 1F62205' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	11 Jan 2021 19:15:19

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:34:19

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14,16,18AUG2020 is recorded under Illness Visit Day 3,5,7 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 06:56:17
User entered '14 Aug 2020' reason for change: Data Entry Error	Jacob sekinger (b) (4)	06 Nov 2020 14:48:28
User entered '13 Aug 2020'	Jacob sekinger (b) (4)	06 Nov 2020 14:46:08

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:34:19

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:46:08

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:34:19

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Steven Anderson (b) (4)	08 Apr 2021 18:08:37
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 14:46:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 14:46:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	06 Nov 2020 14:46:54
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 14:46:08
User entered empty.	Jacob sekinger (b) (4)	06 Nov 2020 14:46:08
	(b) (4)	

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:34:19

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16AUG2020 is recorded under Illness Visit Day 5 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 09:55:43
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16AUG2020 is recorded under Illness Visit Day 5 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'no saliva was returned by the subject' (Site from DM).	Steven Anderson (b) (4) (b) (4)	08 Apr 2021 18:08:47
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4) (b) (4)	08 Apr 2021 18:08:37
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16AUG2020 is recorded under Illness Visit Day 5 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 09:16:50
User entered '16 Aug 2020' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:46:54
User entered empty.	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:46:08

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:34:19

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:46:08

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:34:19

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Steven Anderson (b) (4)	08 Apr 2021 18:09:00
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 14:48:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 14:48:28
User entered 'Yes (Y)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	06 Nov 2020 14:48:28
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 14:46:08
User entered empty.	Jacob sekinger (b) (4)	06 Nov 2020 14:46:08
	(b) (4)	

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:34:19

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18AUG2020 is recorded under Illness Visit Day 7 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 09:55:47
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18AUG2020 is recorded under Illness Visit Day 7 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'no saliva was returned by this subject' (Site from DM).	Steven Anderson (b) (4) (b) (4)	08 Apr 2021 18:09:10
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4) (b) (4)	08 Apr 2021 18:09:00
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18AUG2020 is recorded under Illness Visit Day 7 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 09:17:05
User entered '18 Aug 2020' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:48:28
User entered empty.	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:46:08

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:34:19

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:46:08

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:34:19

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Nov 2020 19:40:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 19:40:24
User entered 'No (N)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	09 Nov 2020 19:40:24
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	06 Nov 2020 14:46:08
User entered empty.	System	06 Nov 2020 14:46:08
	Jacob sekinger (b) (4)	06 Nov 2020 14:46:08
	(b) (4)	

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:34:19

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Jacob sekinger (b) (4)	06 Nov 2020 14:46:08
	(b) (4)	

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:34:19

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:46:08

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:34:19

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 19:40:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 19:40:24
User entered 'No (N)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	09 Nov 2020 19:40:24
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 14:46:08
User entered empty.	Jacob sekinger (b) (4)	06 Nov 2020 14:46:08
	(b) (4)	

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:34:19

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Jacob sekinger (b) (4)	06 Nov 2020 14:46:08
	(b) (4)	

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:34:19

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:46:08

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:34:19

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Nov 2020 19:40:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 19:40:24
User entered 'No (N)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	09 Nov 2020 19:40:24
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	06 Nov 2020 14:46:08
User entered empty.	System	06 Nov 2020 14:46:08
	Jacob sekinger (b) (4)	06 Nov 2020 14:46:08
	(b) (4)	

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:34:19

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Jacob sekinger (b) (4)	06 Nov 2020 14:46:08
	(b) (4)	

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:34:19

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:46:08

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:34:19

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Nov 2020 19:40:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 19:40:24
User entered 'No (N)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	09 Nov 2020 19:40:24
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	06 Nov 2020 14:46:08
User entered empty.	System	06 Nov 2020 14:46:08
	Jacob sekinger (b) (4)	06 Nov 2020 14:46:08
	(b) (4)	

US3412126

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:34:19

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
	(b) (4)	
User entered empty.	Jacob sekinger (b) (4)	06 Nov 2020 14:46:08
	(b) (4)	

US3412126

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:29
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:39:20

US3412126

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:29
User entered '12 Aug 2020'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:39:20

US3412126

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:02:29
User entered 'Clinic (Clinic)'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:39:20

US3412126

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:37
User entered 'SICKD1'	System	06 Nov 2020 14:39:20

US3412126

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:05:45
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:42:04

US3412126

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:05:45
User entered '12 Aug 2020'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:42:04

US3412126

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:05:45
User entered '16:51'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:42:04

US3412126

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:37
User entered '12 Aug 2020 16:51'	System	06 Nov 2020 14:42:04

US3412126

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:05:45
User entered '151' cm	Jacob sekinger (b) (4)	06 Nov 2020 14:42:04
DataPoint set to visible.	(b) (4) System	06 Nov 2020 14:39:20

US3412126

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:05:45
User entered '42' kg	Jacob sekinger (b) (4)	06 Nov 2020 14:42:04
DataPoint set to visible.	(b) (4) System	06 Nov 2020 14:39:20

US3412126

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:05:45
User entered '99.2' F	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:42:04

US3412126

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:05:45
User entered 'Oral (Oral)'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:42:04

US3412126

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:05:45
User entered empty.	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:42:04

US3412126

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:05:45
User entered '90'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:42:04

US3412126

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:37
User entered 'bpm'	System	06 Nov 2020 14:42:04

US3412126

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:05:45
User entered '16'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:42:04

US3412126

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:37
User entered 'breaths/min'	System	06 Nov 2020 14:42:04

US3412126

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:05:45
User entered '128'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:42:04

US3412126

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:37
User entered 'mmHg'	System	06 Nov 2020 14:42:04

US3412126

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:05:45
User entered '80'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:42:04

US3412126

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:37
User entered 'mmHg'	System	06 Nov 2020 14:42:04

US3412126

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:37

US3412126

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:19

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:37

US3412126

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:05:50
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:42:19

US3412126

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:19

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:05:50
User entered '12 Aug 2020'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:42:19

US3412126

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:34:19

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:05:57
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:43:28

US3412126

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:34:19

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:05:57
User entered '12 Aug 2020'	Jacob sekinger (b) (4) (b) (4)	06 Nov 2020 14:43:28

US3412126

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

Form: Visit Date

Generated On: 09 Jun 2021 17:34:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4) (b) (4)	16 Apr 2021 14:22:28
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	31 Mar 2021 19:29:41

US3412126

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

Form: Visit Date

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4) (b) (4)	16 Apr 2021 14:22:28
User entered '24 Feb 2021'	Steven Anderson (b) (4) (b) (4)	31 Mar 2021 19:29:41

US3412126

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

Form: Visit Date

Generated On: 09 Jun 2021 17:34:19

[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 22:53:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4)	31 Mar 2021 19:29:41

US3412126

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

Form: Visit Date

Generated On: 09 Jun 2021 17:34:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered 'UNBLND_DECIDE'	System	31 Mar 2021 19:29:41

US3412126

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

Form: Unblinding

Generated On: 09 Jun 2021 17:34:19

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered '24 Feb 2021'	(b) (4) Steven Anderson (b) (4)	31 Mar 2021 19:29:22

US3412126

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

Form: Unblinding

Generated On: 09 Jun 2021 17:34:19

[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 22:53:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered '0'	Steven Anderson (b) (4)	31 Mar 2021 19:29:22

US3412126

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

Form: Unblinding

Generated On: 09 Jun 2021 17:34:19

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered 'Yes (Y)'	Steven Anderson (b) (4)	31 Mar 2021 19:29:22

US3412126

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

Form: Unblinding

Generated On: 09 Jun 2021 17:34:19

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4) (b) (4)	16 Apr 2021 14:22:28
User entered 'Amendment 6 or later (Amendment 6 or later)'	Steven Anderson (b) (4) (b) (4)	31 Mar 2021 19:29:22

US3412126

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

Form: Unblinding

Generated On: 09 Jun 2021 17:34:19

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered '24 Feb 2021'	(b) (4) Steven Anderson (b) (4)	31 Mar 2021 19:29:22

US3412126

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

Form: Unblinding

Generated On: 09 Jun 2021 17:34:19

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered 'mRNA-1273 (mRNA-1273)'	Steven Anderson (b) (4)	31 Mar 2021 19:29:22

US3412126

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

Form: Unblinding

Generated On: 09 Jun 2021 17:34:19

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered 'mRNA-1273 (mRNA-1273)'	Steven Anderson (b) (4)	31 Mar 2021 19:29:22

US3412126

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

Form: Unblinding

Generated On: 09 Jun 2021 17:34:19

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered 'Not Administered (NA)'	(b) (4) Steven Anderson (b) (4)	31 Mar 2021 19:29:22

US3412126

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

Form: Unblinding

Generated On: 09 Jun 2021 17:34:19

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered 'No (N)'	Steven Anderson (b) (4)	31 Mar 2021 19:29:22

US3412126

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

Form: Unblinding

Generated On: 09 Jun 2021 17:34:19

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered empty.	System	31 Mar 2021 19:29:22

US3412126

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

Form: Unblinding

Generated On: 09 Jun 2021 17:34:19

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered empty.	System	31 Mar 2021 19:29:22

US3412126

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4) (b) (4)	16 Apr 2021 14:22:28
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	31 Mar 2021 19:29:27

US3412126

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:19

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Steven Anderson (b) (4)	31 Mar 2021 19:29:27

US3412126

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	Steven Anderson (b) (4)	31 Mar 2021 19:29:27

US3412126

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered empty.	System	31 Mar 2021 19:29:27

US3412126

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:34:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered 'No (N)'	Steven Anderson (b) (4)	31 Mar 2021 19:29:31

US3412126

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:34:19

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	Steven Anderson (b) (4)	31 Mar 2021 19:29:31

US3412126

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:34:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	(b) (4) Steven Anderson (b) (4)	31 Mar 2021 19:29:31

US3412126

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:34:19

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:53:24
User entered empty.	System	31 Mar 2021 19:29:31

US3412126

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:34:19

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:31
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of MUSCLE ACHES persist beyond Day 7 (start date: Day 3; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 18:34:05
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 1; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 18:34:02
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:06:46
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of MUSCLE ACHES persist beyond Day 7 (start date: Day 3; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'these are symptoms of the AE URI' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	06 Apr 2021 12:26:15
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 1; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'these are symptoms of the AE URI' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	06 Apr 2021 12:26:13
User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of MUSCLE ACHES persist beyond Day 7 (start date: Day 3; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 11:58:09

US3412126

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:34:19

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 1; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	21 Mar 2021 11:57:56
User entered 'Yes (Y)'	Richard Powell (b) (4) (b) (4) (b) (4), (b) (6)	15 Mar 2021 15:31:04 27 Aug 2020 22:24:05

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:19

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:57

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:19

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User closed query 'Per MM, please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known.' (Site from DM). Query 'Per MM, please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known.' answered with 'this was not diagnosed as COVID and no organism was known.' (Site from DM).	(b) (4), (b) (6) Steven Anderson (b) (4) (b) (4)	10 Feb 2021 19:11:04 10 Feb 2021 16:49:01
User opened query 'Per MM, please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known.' (Site from DM). User closed query 'Per MM, Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 10:00:38 20 Oct 2020 10:31:23
Query 'Per MM, Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'arranged for a visit - vis on 12-aug-2020' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 18:53:14
User opened query 'Per MM, Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 06:45:34
User coded data point as SOC: Infections and infestations, HLT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 00:50:14

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:19

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	28 Aug 2020 00:50:14
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	27 Aug 2020 22:26:47
User entered 'Upper Respiratory Infection'	(b) (4), (b) (6)	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered 'Yes (Y)'		27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered 'No (N)'		27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered 'No (N)'		27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered '05 Aug 2020'	(b) (4), (b) (6)	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:19

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:05:51
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Sep 2020 09:15:01
Query 'Data is required. Please provide.' answered with 'SUBJECT DOES NOT RECALL TIME' (Site from System).	Mylene Asmar-Rios (b) (4)	18 Sep 2020 19:01:01
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 22:26:02
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 22:26:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:57
User entered empty.	System	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered 'No (N)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 19:00:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:58:55
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 22:26:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:19

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered '18 Aug 2020' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 19:00:44
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	18 Sep 2020 18:58:55
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	18 Sep 2020 18:58:55
User entered empty; reason for change Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:58:55
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	27 Aug 2020 22:26:36
User entered '18 Aug 2020'	(b) (4), (b) (6)	27 Aug 2020 22:26:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:19

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User closed query 'Data is required. Please provide.' (Site from System).		21 Sep 2020 09:15:03
Query 'Data is required. Please provide.' answered with 'SUBJECT DOES NOT RECALL TIME ' (Site from System).	Mylene Asmar-Rios (b) (4)	18 Sep 2020 19:01:11
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Sep 2020 19:00:44
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Sep 2020 18:58:55
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 22:26:02
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:57
User entered empty.	System	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:19

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered 'Grade 1/Mild (Grade 1/Mild)'		27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered 'No (N)'		27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:19

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered '0'		27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:19

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered '0'		27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 22:26:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:19

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:19

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered empty.		27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered empty.		27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered '0'		27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:19

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered '0'		27 Aug 2020 22:26:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered 'Not Related (NOT RELATED)'		27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	27 Aug 2020 22:26:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:19

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered 'None (NONE)'		27 Aug 2020 22:26:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:19

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered '0' reason for change: Data Entry Error	Melissa Fuson (b) (4)	14 Dec 2020 14:43:39
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	27 Aug 2020 22:26:36
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 22:26:36
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	27 Aug 2020 22:26:02
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 22:26:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered '1' reason for change: Data Entry Error	Melissa Fuson (b) (4)	14 Dec 2020 14:43:39
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered '0'		27 Aug 2020 22:26:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:19

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Mylene Asmar-Rios (b) (4)	18 Sep 2020 19:00:44
Data Entry Error		
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 22:26:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 22:26:36
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	(b) (4), (b) (6)	27 Aug 2020 22:26:36
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 22:26:02
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 22:26:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:19

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered empty.		27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:19

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered empty.		27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:19

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:57
User entered '0'	System	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:19

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:57
User entered '1'	System	27 Aug 2020 22:26:02

US3412126

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:19

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:57

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:19

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:00

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:19

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:00
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User closed query 'Per MM, Please confirm that criteria for discontinuation of study treatment (per section 7.2.) was met.' (Site from DM).		28 Oct 2020 04:21:34
Query 'Per MM, Please confirm that criteria for discontinuation of study treatment (per section 7.2.) was met.' answered with 'UPDATED ALL RECORDS' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 18:12:28
User opened query 'Per MM, Please confirm that criteria for discontinuation of study treatment (per section 7.2.) was met.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 06:49:35
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Musculoskeletal chest pain, LLT: Rib pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 00:50:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 00:50:17
Data point term sent to Coder	System	27 Aug 2020 22:28:53
User entered 'Rib Pain'	(b) (4), (b) (6)	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:00
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:00
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered 'No (N)'		27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:00
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered 'No (N)'		27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:00
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered '23 Aug 2020'		27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:19

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:00
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	27 Aug 2020 22:29:12
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	27 Aug 2020 22:29:12
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 22:29:12
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	27 Aug 2020 22:28:18
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	27 Aug 2020 22:28:18
User entered 'un:un' (non-conformant).	(b) (4), (b) (6)	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:00
User entered empty.	System	27 Aug 2020 22:29:12
User entered '23 Aug 2020 UN:UN' (non-conformant).	System	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:00
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4)	18 Dec 2020 07:38:46
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'AE RECPVERED RESOLVED ON 22-SEP-2020' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 14:11:35
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 14:10:13
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	29 Nov 2020 09:24:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:19

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:00
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Dec 2020 14:11:03
User entered '22 Sep 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 14:11:03
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Dec 2020 14:10:13
User entered '22 2020' (non-conformant).	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 14:10:13
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:19

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:00
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:00
User entered empty.	System	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:19

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:00
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered 'Grade 4 (Grade 4)'		27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:00
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).		28 Aug 2020 19:07:34
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered with 'Subject went to emergency room but PI does not consider serious adverse event' (Site from System).		27 Aug 2020 22:29:04
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).		27 Aug 2020 22:28:18
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:19

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:00
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered '0'		27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:19

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:00
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered '0'		27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:00
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered '0'		27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:19

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:00
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered empty.		27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:19

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:00
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered empty.		27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:00
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered empty.		27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:00
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered empty.		27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:00
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered '0'		27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:00
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered '0'		27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:19

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:00
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered '0'		27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:00
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered 'Not Related (NOT RELATED)'		27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:00
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:19

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:00
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered 'None (NONE)'		27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:19

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:00
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered '0' reason for change: Data Entry Error	Melissa Fuson (b) (4)	11 Jan 2021 19:18:36
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	27 Aug 2020 22:29:12
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 22:29:12
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	27 Aug 2020 22:28:18
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:00
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered '1' reason for change: Data Entry Error	Melissa Fuson (b) (4)	11 Jan 2021 19:18:36
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:00
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered '0'		27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:19

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:00
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 14:11:03
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:19

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:00
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered empty.		27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:19

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:00
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered empty.		27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:19

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:00
User entered '0'	System	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:19

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:00
User entered '1'	System	27 Aug 2020 22:28:18

US3412126

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:34:19

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:00

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:19

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:45:44
Reviewed for Safety.		28 Aug 2020 17:08:26
User entered 'USA-US061-2020-mRNA-1273-P301000004'	System	28 Aug 2020 17:08:18
User entered 'New'	(b) (4), (b) (6)	28 Aug 2020 17:08:18

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:19

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 17:05:06
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Lung abscess, LLT: Abscess of lung - version MedDRA\23.0.	Coder Import (b) (4)	06 Apr 2021 12:35:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	06 Apr 2021 12:35:57
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Lung abscess, LLT: Abscess of lung - version MedDRA\23.0.	Coder Import (b) (4)	06 Apr 2021 12:34:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	06 Apr 2021 12:34:53
Data point term sent to Coder	System	06 Apr 2021 12:34:19
User closed query 'For coding purposes, please split ABSCESS OF LUNG WITH PNEUMONIA into separate entries. 1. ABSCESS OF LUNG and 2. PNEUMONIA' (Site from System).	System	06 Apr 2021 12:34:03
Query 'For coding purposes, please split ABSCESS OF LUNG WITH PNEUMONIA into separate entries. 1. ABSCESS OF LUNG and 2. PNEUMONIA' answered with 'updated' (Site from System).	Andrea Newlands (b) (4)	06 Apr 2021 12:34:03
Data point term sent to Coder	System	06 Apr 2021 12:33:18
DataPoint Un-verified.	Andrea Newlands (b) (4)	06 Apr 2021 12:32:24
Coding entries removed.	(b) (4)	
	Andrea Newlands (b) (4)	06 Apr 2021 12:32:24
	(b) (4)	
User entered 'ABSCESS OF LUNG' reason for change: Data Entry Error	Andrea Newlands (b) (4)	06 Apr 2021 12:32:24
User opened query 'For coding purposes, please split ABSCESS OF LUNG WITH PNEUMONIA into separate entries. 1. ABSCESS OF LUNG and 2. PNEUMONIA' (Site from System).	Coder Import (b) (4)	22 Mar 2021 11:35:44
User closed query 'For coding purposes, please split ABSCESS OF LUNG WITH PNEUMONIA into separate entries.' (Site from Coder).	(b) (4), (b) (6)	22 Mar 2021 11:35:19

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:19

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:15:56
Query 'For coding purposes, please split ABSCESS OF LUNG WITH PNEUMONIA into separate entries.' answered with 'this is the term the PI believes should be listed for this AE' (Site from Coder).	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 20:14:49
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Lung abscess, LLT: Abscess of lung - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Feb 2021 11:23:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Feb 2021 11:23:24
User opened query 'For coding purposes, please split ABSCESS OF LUNG WITH PNEUMONIA into separate entries.' (Site from Coder).	(b) (4), (b) (6)	28 Feb 2021 11:23:00
Data point term sent to Coder	System	18 Feb 2021 19:01:17
DataPoint Un-verified.	Andrea Newlands (b) (4) (b) (4)	18 Feb 2021 19:01:02
Coding entries removed.	Andrea Newlands (b) (4) (b) (4)	18 Feb 2021 19:01:02
User entered 'abscess of lung with PNEUMONIA' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	18 Feb 2021 19:01:02
User closed query 'Per MM, please confirm the action taken with IP, if the event is present at the time scheduled for further dosing, as per protocol 7.2' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 13:19:42
User closed query 'PV Query: Please consider updating event term to Streptococcus pneumoniae pneumonia as per culture results.' (Site from Safety).		12 Nov 2020 01:37:12
Query 'PV Query: Please consider updating event term to Streptococcus pneumoniae pneumonia as per culture results.' answered with 'this will not be updated. Streptococcus pneumoniae pneumonia was not detected in culture.' (Site from Safety).	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 23:11:10
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:05:43
User opened query 'PV Query: Please consider updating event term to Streptococcus pneumoniae pneumonia as per culture results.' (Site from Safety).		30 Oct 2020 19:46:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:19

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'PV Query Please consider updating event term to Streptococcus pneumoniae pneumonia as per culture results.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 16:53:01
Query 'PV Query Please consider updating event term to Streptococcus pneumoniae pneumonia as per culture results.' answered with 'Site has not received the final culture report yet. term will be updated if applicable.' (Site from Safety).	Steven Anderson (b) (4)	21 Oct 2020 19:06:27
Query 'Per MM, please confirm the action taken with IP, if the event is present at the time scheduled for further dosing, as per protocol 7.2' answered with 'Subject is refusing to proceed on with study at this point as she is waiting for a consult with a rheumatologist.' (Site from DM).	Steven Anderson (b) (4)	21 Oct 2020 19:06:07
User opened query 'PV Query Please consider updating event term to Streptococcus pneumoniae pneumonia as per culture results.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 16:08:59
User opened query 'Per MM, please confirm the action taken with IP, if the event is present at the time scheduled for further dosing, as per protocol 7.2' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 06:50:06
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 00:50:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 00:50:25
Data point term sent to Coder	System	27 Aug 2020 22:31:58
User entered 'Pneumonia'	(b) (4), (b) (6)	27 Aug 2020 22:30:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:46:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 22:30:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:46:04
User entered 'No (N)'		27 Aug 2020 22:30:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:46:07
User entered 'No (N)'		27 Aug 2020 22:30:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:29:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:01
DataPoint Un-verified.	(b) (4)	
	Andrea Newlands (b) (4)	16 Apr 2021 15:46:35
Signature has been broken.	(b) (4)	
	Andrea Newlands (b) (4)	16 Apr 2021 15:46:35
User entered '22 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	16 Apr 2021 15:46:35
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
User closed query 'PV Query: Please confirm the start date, since the patient complained severe right rib and chest pain on Aug 22.' (Site from Safety).	(b) (4)	
	(b) (4), (b) (6)	29 Jan 2021 20:33:05
Query 'PV Query: Please confirm the start date, since the patient complained severe right rib and chest pain on Aug 22.' answered with 'even though that was when the symptoms started site is putting the date of confirmed diagnosis. site can change the rib pain ae if applicable. however, the pneumonia date SAE should be kept 23-AUG-2020 as that is the diagnosis date.' (Site from Safety).	Steven Anderson (b) (4)	28 Jan 2021 20:26:36
	(b) (4)	
User opened query 'PV Query: Please confirm the start date, since the patient complained severe right rib and chest pain on Aug 22.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 16:54:36
DataPoint Verified.		04 Nov 2020 16:46:09
User entered '23 Aug 2020'		27 Aug 2020 22:30:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:19

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:46:10
User entered empty.		27 Aug 2020 22:30:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 22:30:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:59:55
DataPoint Un-verified.	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 18:50:06
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 18:50:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:05:57
User entered 'Yes (Y)'		27 Aug 2020 22:30:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:19

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'IQVIA Medical query: Please provide Investigator's rationale for event end dates of 20 Jan 2021 considering that hospital discharge occurred on 01 Sep 2020, symptoms resolved on 10 Sep 2020, and treatment with antibiotics ended on 22 Sep 2020.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 18:36:20
Query 'IQVIA Medical query: Please provide Investigator's rationale for event end dates of 20 Jan 2021 considering that hospital discharge occurred on 01 Sep 2020, symptoms resolved on 10 Sep 2020, and treatment with antibiotics ended on 22 Sep 2020.'	Andrea Newlands (b) (4)	16 Apr 2021 15:09:14
answered with 'subject had multiple followups and did not get the all clear until 20jan2021' (Site from Safety).	(b) (4)	
User opened query 'IQVIA Medical query: Please provide Investigator's rationale for event end dates of 20 Jan 2021 considering that hospital discharge occurred on 01 Sep 2020, symptoms resolved on 10 Sep 2020, and treatment with antibiotics ended on 22 Sep 2020.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 21:15:33
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:59:56
User closed query 'End date is prior to Start date. Please correct.' (Site from System).	System	18 Feb 2021 19:02:21
User entered '20 Jan 2021' reason for change: Data Entry Error	Andrea Newlands (b) (4)	18 Feb 2021 19:02:21
User opened query 'End date is prior to Start date. Please correct.' (Site from System).	System	18 Feb 2021 19:01:32
DataPoint Un-verified.	Andrea Newlands (b) (4)	18 Feb 2021 19:01:32
User entered '20 Jan 2020' reason for change: Data Entry Error	(b) (4)	
User entered '20 Jan 2020' reason for change: Data Entry Error	Andrea Newlands (b) (4)	18 Feb 2021 19:01:32
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	18 Dec 2020 18:09:01

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:19

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'OUTCOME UPDATED TO RECOVERING RESOLOLIVING DUE TO NOTE DATED 16-DEC-2020 IN SUBJECT FOLDER NOTES THEY ARE HAVING A FOLLOW UP CT IN JANUARY OF 2021 AT ST ELIZABETH NORTH.SHE IS UNSURE OF DATE WILL FOLLOW UP IN JANUARY.' (Site from System).	Melissa Fuson (b) (4)	17 Dec 2020 14:18:00
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4)	
User closed query 'PV query: Please clarify when is the start date. November 23 is the hospitalization date.' (Site from Safety).	System	17 Dec 2020 14:15:05
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 13:56:41
		25 Nov 2020 00:49:57
Query 'PV query: Please clarify when is the start date. November 23 is the hospitalization date.' answered with 'this is correct per medical records. Subject went to ER due to sharp pain from coughing. Subject was admitted that night and diagnosed with pneumonia.' (Site from Safety).	Steven Anderson (b) (4)	24 Nov 2020 19:58:52
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4)	
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	24 Nov 2020 19:55:06
User opened query 'PV query: Please clarify when is the start date. November 23 is the hospitalization date.' (Site from Safety).	System	24 Nov 2020 19:55:06
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	20 Nov 2020 23:05:46
DataPoint Un-verified.	System	20 Nov 2020 18:50:06
	Melissa Fuson (b) (4)	20 Nov 2020 18:50:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:19

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '14 Nov 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4)	20 Nov 2020 18:50:06
DataPoint Verified.	(b) (4)	10 Nov 2020 22:05:55
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 06:07:43
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered with 'recovering resolving, updated.' (Site from System).	Jacob sekinger (b) (4)	27 Oct 2020 18:17:08
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	26 Oct 2020 18:21:26
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 22:30:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:19

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:33:35
User entered empty.		27 Aug 2020 22:30:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV query: Please provide the end date, when available. Please do not answer this query until the event has ended.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 21:10:18
User opened query 'PV query: Please provide the end date, when available. Please do not answer this query until the event has ended.' (Site from Safety).		03 Sep 2020 13:34:03
User entered empty.	System	27 Aug 2020 22:30:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:19

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4)	04 Nov 2020 17:33:33
User closed query 'PV query: Please confirm if the event was considered life-threatening as the event was assessed as grade 4. If so, please update the seriousness criteria to include life-threatening. If not, please update the severity grade.' (Site from Safety). Query 'PV query: Please confirm if the event was considered life-threatening as the event was assessed as grade 4. If so, please update the seriousness criteria to include life-threatening. If not, please update the severity grade.' answered with 'AS PER PROTOCOL AND HOSP IS CONSIDERED GRADE 4' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 20:21:11
Query 'Please confirm if the event was considered life-threatening as the event was assessed as grade 4. If so, please update the seriousness criteria to include life-threatening. If not, please update the severity grade.' answered with 'AS PER PROTOCOL AND HOSP IS CONSIDERED GRADE 4' (Site from Safety).	Mylene Asmar-Rios (b) (4)	18 Sep 2020 19:02:17
Query 'Please confirm the event severity of grade 4. Was this event considered life-threatening? If no, please consider updating event to grade 3' canceled (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 18:45:50
User opened query 'PV query: Please confirm if the event was considered life-threatening as the event was assessed as grade 4. If so, please update the seriousness criteria to include life-threatening. If not, please update the severity grade.' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 13:32:43
User opened query 'Please confirm the event severity of grade 4. Was this event considered life-threatening? If no, please consider updating event to grade 3' (Site from CRA).	(b) (4), (b) (6)	31 Aug 2020 18:16:55
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 22:34:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 22:34:34
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 22:34:34
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 22:30:57
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 22:30:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:33:31
User entered 'Yes (Y)'		27 Aug 2020 22:30:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:33:26
User entered '0'		27 Aug 2020 22:30:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
Query 'PV query: Please confirm if the event was considered life-threatening as the event was assessed as grade 4. If so, please update the seriousness criteria to include life-threatening. If not, please update the severity grade.' canceled (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 23:04:15
User opened query 'PV query: Please confirm if the event was considered life-threatening as the event was assessed as grade 4. If so, please update the seriousness criteria to include life-threatening. If not, please update the severity grade.' (Site from Safety).		20 Nov 2020 23:03:40
DataPoint Verified.		04 Nov 2020 17:33:25
User entered '0'		27 Aug 2020 22:30:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:33:23
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	18 Sep 2020 19:08:28
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	18 Sep 2020 19:08:28
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	27 Aug 2020 22:30:57
User entered '1'	(b) (4), (b) (6)	27 Aug 2020 22:30:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:19

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Please consider changing to 23 Aug 2020 since subject was in ER on 22 Aug 2020 - as we discussed' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:11:08
Query 'Please consider changing to 23 Aug 2020 since subject was in ER on 22 Aug 2020 - as we discussed' answered with 'Per our discussion we decided to leave this at 22-aud-20 due to subject never leaving the hospital.' (Site from CRA).	Steven Anderson (b) (4)	21 Apr 2021 14:02:51
User opened query 'Please consider changing to 23 Aug 2020 since subject was in ER on 22 Aug 2020 - as we discussed' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 13:23:01
DataPoint Verified.	(b) (4)	20 Apr 2021 22:29:43
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:01
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	Andrea Newlands (b) (4)	16 Apr 2021 15:47:43
User entered '22 Aug 2020' reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Andrea Newlands (b) (4)	16 Apr 2021 15:47:43
DataPoint Verified.	(b) (4)	
User entered '23 Aug 2020'	Richard Powell (b) (4)	12 Apr 2021 14:09:37
	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 17:33:17
	(b) (4), (b) (6)	27 Aug 2020 22:30:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:19

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4)	04 Nov 2020 17:33:21
User closed query 'PV query: Please provide the discharge date, when available.' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 20:21:25
Query 'PV query: Please provide the discharge date, when available.' answered with '01 SEP 2020' (Site from Safety).	Mylene Asmar-Rios (b) (4)	18 Sep 2020 19:08:42
User entered '01 Sep 2020' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 19:08:28
User opened query 'PV query: Please provide the discharge date, when available.' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 13:35:13
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 22:30:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:33:08
User entered 'No (N)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:10:34
User closed query 'PV Query: Did the subject require admission to the intensive care unit?' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 20:21:33
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 19:23:46
Query 'PV Query: Did the subject require admission to the intensive care unit?' answered with 'NO' (Site from Safety).	Mylene Asmar-Rios (b) (4)	18 Sep 2020 19:12:31
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	18 Sep 2020 19:08:28
Query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).	System	18 Sep 2020 19:08:28
User entered 'No (N)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	18 Sep 2020 19:08:28
User opened query 'PV Query: Did the subject require admission to the intensive care unit?' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 13:33:27
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	27 Aug 2020 22:30:57
User entered 'Unknown (UNK)'	(b) (4), (b) (6)	27 Aug 2020 22:30:57

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Folder: Adverse Events

Form: Adverse Events (3)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:32:59
User closed query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	System	21 Sep 2020 14:10:34
Query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' answered by data change (Site from System).	System	21 Sep 2020 14:10:34
User opened query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	System	18 Sep 2020 19:23:46
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 22:30:57

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:33:02
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 22:30:57

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:33:03
User entered '0'		27 Aug 2020 22:30:57

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Folder: Adverse Events

Form: Adverse Events (3)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:33:05
User entered '0'		27 Aug 2020 22:30:57

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:24:01
User entered 'Not Related (NOT RELATED)'		27 Aug 2020 22:30:57

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Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:24:03
User entered 'Not Related (NOT RELATED)'		27 Aug 2020 22:30:57

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Folder: Adverse Events

Form: Adverse Events (3)

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 18:39:47
DataPoint Un-verified.	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 16:12:17
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 16:12:17
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	25 Nov 2020 03:43:45
DataPoint Verified.		25 Nov 2020 00:51:17
User closed query 'Re-query: Dose discontinuation page is blank. As previously instructed please complete.' (Site from CRA).		25 Nov 2020 00:50:22
User entered 'None (NONE)' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	24 Nov 2020 19:59:23
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'This was updated to other because it was the patients decision to discontinue IP.' (Site from System).	Steven Anderson (b) (4) (b) (4)	24 Nov 2020 19:50:49
Query 'Re-query: Dose discontinuation page is blank. As previously instructed please complete.' answered with 'this has been filled out' (Site from CRA).	Steven Anderson (b) (4) (b) (4)	24 Nov 2020 19:49:08
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	18 Nov 2020 14:11:53
User closed query 'Please update accordingly - subject did not receive Dose 2 - was this due to SAE?' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:50:49
User opened query 'Re-query: Dose discontinuation page is blank. As previously instructed please complete.' (Site from CRA).		16 Nov 2020 02:50:38

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:19

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Please complete Dose Discontinuation CRF in End of Study folder' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:50:38
Query 'Please complete Dose Discontinuation CRF in End of Study folder' answered with 'this has been updated' (Site from CRA).	Steven Anderson (b) (4)	10 Nov 2020 23:15:59
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Steven Anderson (b) (4)	10 Nov 2020 23:15:32
Query 'Please update accordingly - subject did not receive Dose 2 - was this due to SAE?' answered with 'This was due to SAE. subject has not stated that she wants to continue in the study. HOWEVER, she did miss visit 2 dosing due to SAE.' (Site from CRA).	Steven Anderson (b) (4)	10 Nov 2020 23:13:14
User opened query 'Please complete Dose Discontinuation CRF in End of Study folder' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 17:27:04
User opened query 'Please update accordingly - subject did not receive Dose 2 - was this due to SAE?' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 17:25:46
User entered 'None (NONE)'	(b) (4), (b) (6)	27 Aug 2020 22:30:57

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Folder: Adverse Events

Form: Adverse Events (3)

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 04:58:15
User entered '0'		27 Aug 2020 22:30:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
User closed query ' PV Query: Please confirm or correct the start and stop dates of piperacillin and tazobactam in EDC (concomitant medications). ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:20:10
Query ' PV Query: Please confirm or correct the start and stop dates of piperacillin and tazobactam in EDC (concomitant medications). ' answered with 'this has been updated' (Site from Safety).	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 20:18:11
User opened query ' PV Query: Please confirm or correct the start and stop dates of piperacillin and tazobactam in EDC (concomitant medications). ' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:55:45
DataPoint Verified.		29 Dec 2020 14:27:14
User closed query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConMed #12 recorded that machth this AE during this timeframe. Review and update eCRF as appropriate.' (Site from DM).		15 Dec 2020 04:29:17
Query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConMed #12 recorded that machth this AE during this timeframe. Review and update eCRF as appropriate.' answered with 'UPDATED TO CONCOMITANT MEDICATIONS BEING TAKEN' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 14:55:52
User entered '1' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 14:55:03
User opened query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConMed #12 recorded that machth this AE during this timeframe. Review and update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 05:17:36
DataPoint Un-verified.	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 18:51:31
User entered '0' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 04:58:17

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Subject received meds in hospital and discharged on antibiotics - please update to Yes and add all con meds to Con Med CRF' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 04:58:12
Query 'Subject received meds in hospital and discharged on antibiotics - please update to Yes and add all con meds to Con Med CRF' answered with 'this list will be updated' (Site from CRA).	Steven Anderson (b) (4)	10 Nov 2020 23:17:08
User entered '1' reason for change: Data Entry Error	Steven Anderson (b) (4)	10 Nov 2020 23:16:55
User opened query 'Subject received meds in hospital and discharged on antibiotics - please update to Yes and add all con meds to Con Med CRF' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 17:27:57
User entered '0' reason for change: Data Entry Error	Melissa Fuson (b) (4)	26 Oct 2020 18:26:39
User closed query 'PV query: It was noted that the subject received IV antibiotics. Please add antibiotic details to CM eCRF (including dates of administration, dose, units, frequency, route, indication).' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 20:21:42
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4)	20 Sep 2020 20:21:39
Query 'PV query: It was noted that the subject received IV antibiotics. Please add antibiotic details to CM eCRF (including dates of administration, dose, units, frequency, route, indication).' answered with 'OK' (Site from Safety).	Mylene Asmar-Rios (b) (4)	18 Sep 2020 19:14:02
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with 'OK' (Site from Safety).	Mylene Asmar-Rios (b) (4)	18 Sep 2020 19:13:58

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Query 'Per ETRTR: Please ensure reporting on EDC CRF ConMeds page treatment during hospitalization and home treatment, thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 18:47:16
User opened query 'PV query: It was noted that the subject received IV antibiotics. Please add antibiotic details to CM eCRF (including dates of administration, dose, units, frequency, route, indication).' (Site from Safety).		03 Sep 2020 13:38:06
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).		03 Sep 2020 13:32:03
User opened query 'Per ETRTR: Please ensure reporting on EDC CRF ConMeds page treatment during hospitalization and home treatment, thanks.' (Site from CRA).		31 Aug 2020 18:23:11
User entered '1'		27 Aug 2020 22:30:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
User closed query 'Per DM CLR - RQ: Site's response noted. However, the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field.' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 05:00:01
Query 'Per DM CLR - RQ: Site's response noted. However, the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field.' answered with 'no medical procedure has been noted. Subject only received medication for treatments site removed con procedure. However, this seems inconsistent with other SAE's as we have been told to list diagnostic procedures as well' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6) Steven Anderson (b) (4)	15 Mar 2021 21:16:33 15 Mar 2021 20:20:01
User entered '0' reason for change: Data Entry Error	Steven Anderson (b) (4)	15 Mar 2021 20:19:26
User opened query 'Per DM CLR - RQ: Site's response noted. However, the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field.' (Site from DM). User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 08:24:30 19 Feb 2021 04:29:09

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'con procedures form has been filled out and all data has been entered' (Site from DM).	Steven Anderson (b) (4) (b) (4)	18 Feb 2021 14:45:35
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 04:25:44
		11 Nov 2020 04:58:45
User entered '1' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 18:26:39
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Aug 2020 22:30:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:19

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:59:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	18 Feb 2021 14:45:55
DataPoint Un-verified.	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 14:15:05
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 14:15:05
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 13:56:47 25 Nov 2020 00:51:27
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Subject has recovered as of 14nov2020' (Site from Safety). DataPoint Un-verified.	Steven Anderson (b) (4) (b) (4)	24 Nov 2020 19:55:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	24 Nov 2020 19:55:06
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:05:00 11 Nov 2020 04:58:49
User closed query 'Per source not on 15 Oct 2020, subject symptoms returned to baseline - should end date be added and outcome resolved?' (Site from CRA).		11 Nov 2020 04:58:41

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Folder: Adverse Events

Form: Adverse Events (3)

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[Outcome](#)

Audit	User	Time (GMT)
Query 'Per source not on 15 Oct 2020, subject symptoms returned to baseline - should end date be added and outcome resolved?' answered with 'CRC's note is unclear and subject is still having problems requiring doctors visits and CT scans. site is trying to follow up with patient but she will not allow medical records to be obtained.' (Site from CRA).	Steven Anderson (b) (4)	10 Nov 2020 23:23:47
User opened query 'Per source not on 15 Oct 2020, subject symptoms returned to baseline - should end date be added and outcome resolved?' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 17:21:38
Query 'PV Query: Query response states that outcome is resolved; however, outcome field not updated in EDC. If outcome is resolved, please update field in EDC. If not resolved, please leave this query open until information is available.' canceled (Site from Safety).	(b) (4)	28 Oct 2020 17:15:36
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	27 Oct 2020 18:18:41
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	26 Oct 2020 18:21:26
User opened query 'PV Query: Query response states that outcome is resolved; however, outcome field not updated in EDC. If outcome is resolved, please update field in EDC. If not resolved, please leave this query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 16:08:04
User closed query 'PV query: Please provide the final outcome, when available. Please do not answer this query until the event has ended.' (Site from Safety).	(b) (4)	02 Oct 2020 12:55:22
Query 'PV query: Please provide the final outcome, when available. Please do not answer this query until the event has ended.' answered with 'resolved' (Site from Safety).	Mylene Asmar-Rios (b) (4)	01 Oct 2020 14:11:15
User opened query 'PV query: Please provide the final outcome, when available. Please do not answer this query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	03 Sep 2020 13:34:45

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Folder: Adverse Events

Form: Adverse Events (3)

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[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	27 Aug 2020 22:30:57

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Folder: Adverse Events

Form: Adverse Events (3)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 04:58:54
User entered empty.		27 Aug 2020 22:30:57

US3412126

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:19

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
User closed query 'PV Query: Please provide information on the clinical details after discharge (01 Sep2020) until resolution (20Jan2021). ' (Site from Safety). User closed query 'Per DM CLR: Narrative = SHE IS A SMOKER. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:20:21 16 Mar 2021 04:58:29
Query 'Per DM CLR: Narrative = SHE IS A SMOKER. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' answered with 'this has been added into medical history' (Site from DM).	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 20:22:32
Query 'PV Query: Please provide information on the clinical details after discharge (01 Sep2020) until resolution (20Jan2021). ' answered with 'Site can not update anything else as the word limit is reached' (Site from Safety). DataPoint Verified.	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 20:20:27
User closed query 'Please consider re-writing narrative to provide complete chronology of SAE ' (Site from CRA).	(b) (4), (b) (6)	02 Mar 2021 16:46:41
User opened query 'Per DM CLR: Narrative = SHE IS A SMOKER. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:46:30
User opened query 'PV Query: Please provide information on the clinical details after discharge (01 Sep2020) until resolution (20Jan2021). ' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 08:23:42
	(b) (4), (b) (6)	25 Feb 2021 18:14:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:34:19

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm that the fever and chills which occurred 4-5 days after investigational product meet criteria of AE/SAE.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 11:05:46
User closed query 'PV Query: Aspirin and benzonatate was prescribed until Aug 18 for URI. Does the URI meet the criteria of AE/SAE or the beginning symptoms of the reported event?' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 11:05:43
User closed query 'PV Query: Please provide information on the clinical details after discharge until resolution.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 11:05:42
User closed query 'PV Query: Please confirm the intraparenchymal abscess meets criteria of AE/SAE. If not, please explain.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 11:05:40
Query 'Please consider re-writing narrative to provide complete chronology of SAE ' answered with 'Narrative has been updated with an overview. site ran out of space due to having to put in all imaging and procedures and their results' (Site from CRA).	Steven Anderson (b) (4) (b) (4)	18 Feb 2021 15:20:18
Query 'PV Query: Please confirm that the fever and chills which occurred 4-5 days after investigational product meet criteria of AE/SAE.' answered with 'site does not believe this is an AE due to the pneumonia causing these fever and chills. ' (Site from Safety).	Steven Anderson (b) (4) (b) (4)	18 Feb 2021 15:19:41
Query 'PV Query: Please provide information on the clinical details after discharge until resolution.' answered with 'this information has been added' (Site from Safety).	Steven Anderson (b) (4) (b) (4)	18 Feb 2021 15:18:43

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
User entered (b) (6) FEMALE WITH CHEST PAIN. PT HAS SEVERE, SHARP PAIN, WORSE WITH COUGHING. PAIN LOCATED ON RIGHT SIDE. PT HAD PAIN STARTING THE FOLLOWING DAY. FELT LIKE SHE HAD A BROKEN RIB. SHE IS A SMOKER. ASSOCIATED SYMPTOMS INCLUDE POOR APPETITE, DYSPNEA. PATIENT WAS FOUND TO HAVE CAVITARY PNA. NOW S/P BRONCH. ID ON BOARD FOR ABX MANAGMENT. PLAN FOR LONG TERM IV ABX AT HOME (ZOSYN) FOR AN ADDITIONAL 3 WEEKS. CRX WITH STABLE EXTENSIVE R MIDDLE LOBE INFILTRATE/ CONSOLIDATION WITH KNOWN INTRAPARENCHYMAL ABSCESS. INITIAL LABS SHOWED LEUCOCYTOSIS, BLOOD CX SO FAR NGTD. CT SHOWED MULTIFOCAL CONSOLIDATION AND FLUID IN THE RML CONCERNING FOR ABSCESS. SEEN BY PULMONOLOGY, UNDERWENT BRONCHOSCOPY WITH BAL ON 8/25/20. BAL CULTURES AND CYTOLOGY PENDING ID WAS CONSULTED FOR ANTIBIOTIC MANAGEMENT. CULTURE RESULTS STAPHYLOCOCCUS AUREUS WAS NOT DETECTED STREP PNEUMO ANTIGEN WAS NOT DETECTED LEGIONELLA ANTIGEN URINE WAS NOT DETCTED LOWER REPIRATORY CULTURE NO WBC'S SEEN AND NO ORGANISMS SEEN. RESP VIRUS RSP FAC SOURCE = BAL INFLUENZA A-DFA NEGATIVE INFLUENZA B-DFA NEGATIVE PARAINFLUENZA 1- DFA NEGATIVE PARAINFLUENZA 2-DFA NEGATIVE PARAINFLUENZA 3- DFA NEGATIVE ADENOVIRUS- DFA NEGATIVE RSV-DFA NEGATIVE HUMAN METAPNEUMOVIRUS - DFA NEGATIVE FUNGUS CULTURE POSITIVE GROWTH SPARSE GROWTH OF YEAST,	Steven Anderson (b) (4) (b) (4)	18 Feb 2021 15:17:25

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
SUSPECT CANDIDA SPECIES, POSSIBLE REPARATORY TRACT COLON Overview: SUBject was admitted from 8/23/20 - 9/01/2020 in which she presented for evaluation of a dry cough and chest/rib pain. The symptoms were described as ongoing and progressively worsening, chest imaging was obtained and revealed multifocal consolidation and fluid in the right middle lobe concerning for an abscess, Infectious disease was consulted for antibiotic management. She was medically cleared for discharge on 9/1/20and received IV Zosyn until 9/22/20. As of 9/10/20 subject did not report any fever, chills, nausea, vomiting, or diarrhea. Subject has follow ups that have come back without concern' reason for change: Data Entry Error		
Query 'PV Query: Please confirm the intraparenchymal abscess meets criteria of AE/SAE. If not, please explain.' answered with 'this does meet criteria as an AE and will be written up as one' (Site from Safety).	Steven Anderson (b) (4) (b) (4)	18 Feb 2021 15:04:42
Query 'PV Query: Aspirin and benzonatate was prescribed until Aug 18 for URI. Does the URI meet the criteria of AE/SAE or the beginning symptoms of the reported event?' answered with 'uri is already reported as an ae in the system' (Site from Safety).	Steven Anderson (b) (4) (b) (4)	18 Feb 2021 14:48:12
User opened query 'Please consider re-writing narrative to provide complete chronology of SAE ' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 14:49:04
User opened query ' PV Query: Please confirm that the fever and chills which occurred 4-5 days after investigational product meet criteria of AE/SAE.' (Site from Safety).		21 Dec 2020 16:55:07
User opened query 'PV Query: Aspirin and benzonatate was prescribed until Aug 18 for URI. Does the URI meet the criteria of AE/SAE or the beginning symptoms of the reported event?' (Site from Safety).		21 Dec 2020 16:54:04
User opened query 'PV Query: Please provide information on the clinical details after discharge until resolution.' (Site from Safety).		21 Dec 2020 16:53:43

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Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm the intraparenchymal abscess meets criteria of AE/SAE. If not, please explain.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 16:53:20
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 15:35:48
User closed query 'Per DM CLR: SAE Narrative = SHE STATED SHE WENT TO THE EMERGENCY ROOM ON 23AUG2020 FOR RIB PAIN FROM COUGHING. SHE THOUGHT SHE BROKE A RIB AND WANTED TO GET IT WRAPPED. SHE STATED THAT THEY DID A CHEST X-RAY AND WAS DIAGNOSED WITH PNEUMONIA. However, X-Ray date on ConProc eCRF was 22AUG2020. Please review and reconcile data as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 15:35:38
User closed query 'Per DM CLR: SAE Narrative = INITIAL LABS SHOWED LEUCOCYTOSIS, BLOOD CX SO FAR NGTD. However, these were not recorded in the ConProc eCRF. Please review and ensure that these were captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 04:13:34
User closed query 'Per DM CLR: SAE Narrative = BAL CULTURES AND CYTOLOGY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 04:13:14
Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' answered with 'UPDATED CON PROCEDURES' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 16:20:33

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: SAE Narrative = BAL CULTURES AND CYTOLOGY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'UPDATED CON PROCEDURES' (Site from DM).	Melissa Fuson (b) (4)	14 Dec 2020 16:19:05
Query 'Per DM CLR: SAE Narrative = INITIAL LABS SHOWED LEUCOCYTOSIS, BLOOD CX SO FAR NGTD. However, these were not recorded in the ConProc eCRF. Please review and ensure that these were captured in the appropriate eCRF. ' answered with 'UPDATED CON PROCEDURES' (Site from DM).	Melissa Fuson (b) (4)	14 Dec 2020 16:18:57
Query 'Per DM CLR: SAE Narrative = SHE STATED SHE WENT TO THE EMERGENCY ROOM ON 23AUG2020 FOR RIB PAIN FROM COUGHING. SHE THOUGHT SHE BROKE A RIB AND WANTED TO GET IT WRAPPED. SHE STATED THAT THEY DID A CHEST X-RAY AND WAS DIAGNOSED WITH PNEUMONIA. However, X-Ray date on ConProc eCRF was 22AUG2020. Please review and reconcile data as appropriate. ' answered with 'ACCORDING TO THE SOURCE OF MEDICAL RECORDS. THE PROCEDURES WERE DONE ON 22-AUG-2020 BUT SHE WAS NOT ADMITTED TO 23-AUG-2020' (Site from DM).	Melissa Fuson (b) (4)	14 Dec 2020 15:03:03
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 05:17:23
User opened query 'Per DM CLR: SAE Narrative = BAL CULTURES AND CYTOLOGY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 05:17:17

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Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = INITIAL LABS SHOWED LEUCOCYTOSIS, BLOOD CX SO FAR NGTD. However, these were not recorded in the ConProc eCRF. Please review and ensure that these were captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 05:17:13
User opened query 'Per DM CLR: SAE Narrative = SHE STATED SHE WENT TO THE EMERGENCY ROOM ON 23AUG2020 FOR RIB PAIN FROM COUGHING. SHE THOUGHT SHE BROKE A RIB AND WANTED TO GET IT WRAPPED. SHE STATED THAT THEY DID A CHEST X-RAY AND WAS DIAGNOSED WITH PNEUMONIA. However, X-Ray date on ConProc eCRF was 22AUG2020. Please review and reconcile data as appropriate. ' (Site from DM).		10 Dec 2020 05:16:30
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' canceled (Site from Safety).		20 Nov 2020 23:04:38
Query 'PV Query: Did the subject require admission to the intensive care unit?' canceled (Site from Safety).		20 Nov 2020 23:04:22
User opened query 'PV Query: Did the subject require admission to the intensive care unit?' (Site from Safety).		20 Nov 2020 23:03:49
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).		20 Nov 2020 23:03:09
User closed query 'please clarify narrative - (b) (6) (b) (6) ; also subject had bronchoscopy not endoscopy. add status update after post-discharge antibiotics' (Site from CRA).		16 Nov 2020 02:50:12
User closed query 'PV Query: Please provide the site of the cultures from 25 Aug 2020 revealing step pneumo (i.e. sputum, blood, etc).' (Site from Safety).		12 Nov 2020 01:37:27

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Audit	User	Time (GMT)
User closed query 'PV Query: (b) (6) (b) (6) (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 01:37:22
User closed query 'please rewrite narrative to provide complete picture of events - include culture results, etc, ' (Site from CRA).	(b) (4)	11 Nov 2020 04:59:08
Query 'please rewrite narrative to provide complete picture of events - include culture results, etc, ' answered with 'updated' (Site from CRA).	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 23:56:43
Query 'please clarify narrative - (b) (6) (b) (6) ; also subject had bronchoscopy not endoscopy. add status update after post-discharge antibiotics' answered with 'updated' (Site from CRA).	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 23:56:39

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Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'CALLED AND SPOKE TO SUBJECT. SHE STATED SHE WENT TO THE EMERGENCY ROOM ON 23AUG2020 FOR RIB PAIN FROM COUGHING. SHE THOUGHT SHE BROKE A RIB AND WANTED TO GET IT WRAPPED. SHE STATED THAT THEY DID A CHEST X-RAY AND WAS DIAGNOSED WITH PNEUMONIA AND ADMITTED TO ST ELIZABETH HOSPITAL FOR IV ANTIBIOTICS. bronchoscopy WAS DONE ON 25AUG2020 AND WAITING FOR CULTURE RESULTS PER SUBJECT. SHE SAID THEY WILL DISCHARGE HER ONCE THEY GET THE CULTURE RESULTS, THEY CAN PUT HER ON THE CORRECT ANTIBIOTICS FOR HOME. SUBJECT STATED FEELING MUCH BETTER AND COUGH IS MUCH IMPROVED. UPDATE: (b) (6) FEMALE WITH CHEST PAIN. PT HAS SEVERE, SHARP PAIN, WORSE WITH COUGHING. PAIN LOCATED ON RIGHT SIDE. PT WAS GIVEN COVID 19 VACCINE ON 8/4/20 AND HAD PAIN STARTING THE FOLLOWING DAY. FELT LIKE SHE HAD A BROKEN RIB. SHE IS A SMOKER. ASSOCIATED SYMPTOMS INCLUDE POOR APPETITE, DYSPNEA. PATIENT WAS FOUND TO HAVE CAVITARY PNA. NOW S/P BRONCH. ID ON BOARD FOR ABX MANAGMENT. PLAN FOR LONG TERM IV ABX AT HOME (ZOSYN) FOR AN ADDITIONAL 3 WEEKS. CRX WITH STABLE EXTENSIVE R MIDDLE LOVE INFILTRATE/ CONSOLIDATION WITH KNOWN INTRAPARENCHYMAL ABSCESS. Initial labs showed leucocytosis, blood cx so far ngt. ct showed multifocal consolidation and fluid in the RML concerning for abscess. seen by pulmonology, underwent bronchoscopy with BAL on 8/25/20. BAL cultures and cytology pending ID was consulted for antibiotic management. Culture results Staphylococcus aureus was not detected strep pneumo antigen was not	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 23:56:34

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[Narrative](#)

Audit	User	Time (GMT)
detected legionella antigen urine was not detected Lower respiratory culture no WBC's seen and no organisms seen. Resp virus RSP fac source = BAL influenza a-DFA negative influenza b-DFA negative Parainfluenza 1- DFA negative Parainfluenza 2-DFA negative Parainfluenza 3- DFA negative Adenovirus- DFA negative RSV-DFA negative Human metapneumovirus - DFA negative Fungus culture positive growth sparse growth of yeast, suspect candida species, possible reparatory tract colon' reason for change: Data Entry Error Query 'PV Query: Please provide the site of the cultures from 25 Aug 2020 revealing step pneumo (i.e. sputum, blood, etc).' answered with 'no cultures obtained from site indicated strep pneumo... this was not indicated by any means' (Site from Safety). Query 'PV Query: (b) (6) (b) (6) (Site from Safety).	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 23:30:17
(b) (6) (Site from Safety).	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 23:29:09
User opened query 'please rewrite narrative to provide complete picture of events - include culture results, etc, ' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 18:38:48
User opened query 'please clarify narrative - (b) (6) (b) (6) ; also subject had bronchoscopy not endoscopy. add status update after post-discharge antibiotics' (Site from CRA).		04 Nov 2020 17:23:53
User closed query 'Please update narrative per hospital records ' (Site from CRA).		04 Nov 2020 17:23:53
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).		02 Nov 2020 23:27:40
User opened query 'PV Query: (b) (6) (b) (6) (Site from Safety).		30 Oct 2020 19:46:59
User opened query 'PV Query: Please provide the site of the cultures from 25 Aug 2020 revealing step pneumo (i.e. sputum, blood, etc).' (Site from Safety).		30 Oct 2020 19:46:22

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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 'PER EDC QUERY SITE IS FAXING MEDICAL RECORDS OBTAINED FOR SUBJECT US3412126 TO DATA SAFETY TEAM PER STEVEN ANDERSON 21-OCT-20' (Site from Safety).	Melissa Fuson (b) (4)	30 Oct 2020 18:00:07
User closed query 'PV Query: Please provide the site of the cultures from 25 Aug 2020 revealing step pneumo (i.e. sputum, blood, etc).'	(b) (4), (b) (6)	22 Oct 2020 16:53:11
Query 'PV Query: Please provide the site of the cultures from 25 Aug 2020 revealing step pneumo (i.e. sputum, blood, etc).'	Steven Anderson (b) (4)	21 Oct 2020 19:19:59
Query 'Please update narrative per hospital records ' answered with 'narrative has been updated' (Site from CRA).	Steven Anderson (b) (4)	21 Oct 2020 19:19:25

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Form: Adverse Events (3)

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Audit	User	Time (GMT)
User entered 'CALLED AND SPOKE TO SUBJECT. SHE STATED SHE WENT TO THE EMERGENCY ROOM ON 23AUG2020 FOR RIB PAIN FROM COUGHING. SHE THOUGHT SHE BROKE A RIB AND WANTED TO GET IT WRAPPED. SHE STATED THAT THEY DID A CHEST X-RAY AND WAS DIAGNOSED WITH PNEUMONIA AND ADMITTED TO ST ELIZABETH HOSPITAL FOR IV ANTIBIOTICS. ENDOSCOPY WAS DONE ON 25AUG2020 AND WAITING FOR CULTURE RESULTS PER SUBJECT. SHE SAID THEY WILL DISCHARGE HER ONCE THEY GET THE CULTURE RESULTS, THEY CAN PUT HER ON THE CORRECT ANTIBIOTICS FOR HOME. SUBJECT STATED FEELING MUCH BETTER AND COUGH IS MUCH IMPROVED. Update: (b) (6) female with chest pain. Pt has severe, sharp pain, worse with coughing. Pain located on right side. Pt was given COVID 19 vaccine on 8/4/20 and had pain starting the following day. Felt like she had a broken rib. She is a smoker. associated symptoms include poor appetite, dyspnea. Patient was found to have cavitory PNA. Now s/p bronch. ID on board for abx managment. plan for long term IV abx at home (zosyn) for an additional 3 weeks. CRX with stable extensive R middle love infiltrate/ consolidation with known intraparenchymal abscess.' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	21 Oct 2020 19:19:12
User closed query 'Per DM CLR: SAE Narrative contains medications and procedures. Please make sure that these information are recorded in their respective eCRFs. Otherwise, clarify the inconsistencies. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 06:55:37
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).		09 Oct 2020 16:10:32

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

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Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the site of the cultures from 25 Aug 2020 revealing step pneumo (i.e. sputum, blood, etc).' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 16:08:37
User opened query 'Please update narrative per hospital records ' (Site from CRA).	(b) (4), (b) (6)	07 Oct 2020 18:19:09
User closed query 'PV Query: Subject's D-dimer was elevated at 1,911. Please clarify if thromboembolic events were excluded.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 12:55:25
User closed query 'PV query: Please specify the cultures taken on 25 Aug 2020 and provide their results when available.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 12:55:24
Query 'PV Query: Subject's D-dimer was elevated at 1,911. Please clarify if thromboembolic events were excluded.' answered with 'no thromboembolic diagnosis' (Site from Safety).	Mylene Asmar-Rios (b) (4)	01 Oct 2020 14:17:35
Query 'PV query: Please specify the cultures taken on 25 Aug 2020 and provide their results when available.' answered with 'strep pneumo' (Site from Safety).	Mylene Asmar-Rios (b) (4)	01 Oct 2020 14:17:14
Query 'Per DM CLR: SAE Narrative contains medications and procedures. Please make sure that these information are recorded in their respective eCRFs. Otherwise, clarify the inconsistencies.' answered with 'ok' (Site from DM).	Mylene Asmar-Rios (b) (4)	01 Oct 2020 14:11:36
User opened query 'PV Query: Subject's D-dimer was elevated at 1,911. Please clarify if thromboembolic events were excluded.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 19:06:06
User opened query 'PV query: Please specify the cultures taken on 25 Aug 2020 and provide their results when available.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 19:05:53
User opened query 'Per DM CLR: SAE Narrative contains medications and procedures. Please make sure that these information are recorded in their respective eCRFs. Otherwise, clarify the inconsistencies.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 07:27:41
User closed query 'PV query: Please indicate if the subject was tested for COVID when these symptoms appeared.' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 13:11:16

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Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the subject's oxygen saturation level (including date). Did the subject require supplemental oxygen on admission or during hospitalization? If so, please provide the oxygen device , liters of oxygen or FiO2. Has the oxygen been weaned off?' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 13:11:13
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 13:11:11
User closed query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 13:11:09
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Pt. has finds bilaterally pneumonia. Questionable abscess. Elevated WBC 21.8, D dimer 1,911. ' (Site from Safety).	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:22:36
Query 'PV query: Please indicate if the subject was tested for COVID when these symptoms appeared.' answered with 'As per Hospital records patient was COVID-19 negative on 22 AUG 2020' (Site from Safety).	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:16:06
Query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' answered with 'As per Hospital Records 22 AUG 2020 patient tested negative for COVID-19' (Site from Safety).	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:15:30
Query 'PV Query: Please provide the subject's oxygen saturation level (including date). Did the subject require supplemental oxygen on admission or during hospitalization? If so, please provide the oxygen device , liters of oxygen or FiO2. Has the oxygen been weaned off?' answered with 'Oxygen levels were 98% no supplement oxygen was needed. ' (Site from Safety).	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:07:39
User closed query 'PV query: Please provide the results of the endoscopy performed on 25 Aug 2020.' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 20:21:50

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Audit	User	Time (GMT)
Query 'PV query: Please provide the results of the endoscopy performed on 25 Aug 2020.' answered with 'ENDOBONCHIAL FINDINGS : NO MASSES. THE FOLLOWING: TRACHEA, CARINA, RIGHT MAIN BRONCHUS, RIGHT UPPER LOBE BRONCHUS, RIGHT MIDDLE LOBE BRONCHIUS, RIGHT LOWER LOBE BRONCHUS ALL SHOW NORMAL MUCOSA. ' (Site from Safety).	Mylene Asmar-Rios (b) (4)	18 Sep 2020 19:23:28
Query 'Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 18:47:21
Query 'Per ETRTR: Please confirm within Narrative the date of site call contact with subject (date of site awareness), thanks.' canceled (Site from CRA).		06 Sep 2020 18:47:20
Query 'Per ETRTR: Please confirm whether subject was tested for COVID-19 and provide results, thanks.' canceled (Site from CRA).		06 Sep 2020 18:47:19
User opened query 'PV query: Please indicate if the subject was tested for COVID when these symptoms appeared.' (Site from Safety).		03 Sep 2020 13:39:18
User opened query 'PV Query: Please provide the subject's oxygen saturation level (including date). Did the subject require supplemental oxygen on admission or during hospitalization? If so, please provide the oxygen device , liters of oxygen or FiO2. Has the oxygen been weaned off?' (Site from Safety).		03 Sep 2020 13:38:39
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		03 Sep 2020 13:37:37
User opened query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).		03 Sep 2020 13:37:07
User opened query 'PV query: Please provide the results of the endoscopy performed on 25 Aug 2020.' (Site from Safety).		03 Sep 2020 13:36:05
User opened query 'Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from CRA).		31 Aug 2020 18:21:54

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EAB) (1725)

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Audit	User	Time (GMT)
User opened query 'Per ETRTR: Please confirm within Narrative the date of site call contact with subject (date of site awareness), thanks.' (Site from CRA).	(b) (4), (b) (6)	31 Aug 2020 18:21:19
User opened query 'Per ETRTR: Please confirm whether subject was tested for COVID-19 and provide results, thanks.' (Site from CRA).	(b) (4), (b) (6)	31 Aug 2020 18:19:46
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	27 Aug 2020 22:34:34
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	27 Aug 2020 22:34:34
User entered 'Called and spoke to subject. She stated she went to the emergency room on 23Aug2020 for rib pain from coughing. She thought she broke a rib and wanted to get it wrapped. She stated that they did a chest x-ray and was diagnosed with pneumonia and admitted to St Elizabeth hospital for IV antibiotics. Endoscopy was done on 25Aug2020 and waiting for culture results per subject. She said they will discharge her once they get the culture results, they can put her on the correct antibiotics for home. Subject stated feeling much better and cough is much improved. Will request discharge summary,' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 22:34:34
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	27 Aug 2020 22:30:57
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 22:30:57

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 22:30:57

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Folder: Adverse Events

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Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 22:30:57

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Folder: Adverse Events

Form: Adverse Events (3)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Sep 2020 14:10:34
User entered '1'	System	18 Sep 2020 19:23:46
User entered '0'	System	27 Aug 2020 22:30:57

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Folder: Adverse Events

Form: Adverse Events (4)

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[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:28:59
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:00:41
User entered 'USA-US061-2020-mRNA-1273-P301000004'		07 Apr 2021 14:00:26

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Folder: Adverse Events

Form: Adverse Events (4)

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[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:46:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:46:01
Data point term sent to Coder	System	06 Apr 2021 12:44:31
User entered 'pneumonia'	Andrea Newlands (b) (4) (b) (4)	06 Apr 2021 12:43:32

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Folder: Adverse Events

Form: Adverse Events (4)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	06 Apr 2021 12:43:32

US3412126

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	06 Apr 2021 12:43:32

US3412126

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	06 Apr 2021 12:43:32

US3412126

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:29:10
User closed query 'PV Query: Start date of pneumonia was reported as 23 Aug 2020. On 22 Aug 2020, a chest x-ray indicated cavitory bilateral pneumonia. Please consider adjusting start date of event to date of discovery.' (Site from Safety). User signature succeeded.	(b) (4)	19 Apr 2021 18:35:39
	Richard Powell (b) (4)	16 Apr 2021 18:16:01
	(b) (4)	
Query 'PV Query: Start date of pneumonia was reported as 23 Aug 2020. On 22 Aug 2020, a chest x-ray indicated cavitory bilateral pneumonia. Please consider adjusting start date of event to date of discovery.' answered with 'updated' (Site from Safety).	Andrea Newlands (b) (4)	16 Apr 2021 15:48:03
	(b) (4)	
DataPoint Un-verified.	Andrea Newlands (b) (4)	16 Apr 2021 15:47:59
	(b) (4)	
Signature has been broken.	Andrea Newlands (b) (4)	16 Apr 2021 15:47:59
	(b) (4)	
User entered '22 Aug 2020' reason for change: Data Entry Error	Andrea Newlands (b) (4)	16 Apr 2021 15:47:59
	(b) (4)	
User opened query 'PV Query: Start date of pneumonia was reported as 23 Aug 2020. On 22 Aug 2020, a chest x-ray indicated cavitory bilateral pneumonia. Please consider adjusting start date of event to date of discovery.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6)	15 Apr 2021 21:13:41
	(b) (4)	
	Richard Powell (b) (4)	12 Apr 2021 14:09:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:05:51
	(b) (4)	
User entered '23 Aug 2020'	Andrea Newlands (b) (4)	06 Apr 2021 12:43:32
	(b) (4)	

US3412126

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:19

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered empty.	Andrea Newlands (b) (4) (b) (4)	06 Apr 2021 12:43:32

US3412126

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 12:43:32

US3412126

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	06 Apr 2021 12:43:32

US3412126

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:19

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'IQVIA Medical query: Please provide Investigator's rationale for event end dates of 20 Jan 2021 considering that hospital discharge occurred on 01 Sep 2020, symptoms resolved on 10 Sep 2020, and treatment with antibiotics ended on 22 Sep 2020.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 18:36:01
Query 'IQVIA Medical query: Please provide Investigator's rationale for event end dates of 20 Jan 2021 considering that hospital discharge occurred on 01 Sep 2020, symptoms resolved on 10 Sep 2020, and treatment with antibiotics ended on 22 Sep 2020.' answered with 'subject had multiple followups and did not receive the all clear until this date' (Site from Safety).	Andrea Newlands (b) (4) (b) (4)	16 Apr 2021 15:10:18
User opened query 'IQVIA Medical query: Please provide Investigator's rationale for event end dates of 20 Jan 2021 considering that hospital discharge occurred on 01 Sep 2020, symptoms resolved on 10 Sep 2020, and treatment with antibiotics ended on 22 Sep 2020.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 21:14:58
User signature succeeded.	Richard Powell (b) (4) (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered '20 Jan 2021'	Andrea Newlands (b) (4) (b) (4)	06 Apr 2021 12:43:32

US3412126

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:19

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered empty.	Andrea Newlands (b) (4) (b) (4)	06 Apr 2021 12:43:32

US3412126

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 12:43:32

US3412126

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:19

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered 'Grade 4 (Grade 4)'	Andrea Newlands (b) (4) (b) (4)	06 Apr 2021 12:43:32

US3412126

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	06 Apr 2021 12:43:32

US3412126

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered '0'	Andrea Newlands (b) (4) (b) (4)	06 Apr 2021 12:43:32

US3412126

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered '0'	Andrea Newlands (b) (4) (b) (4)	06 Apr 2021 12:43:32

US3412126

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
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).	System	06 Apr 2021 12:49:02
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	06 Apr 2021 12:49:02
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	06 Apr 2021 12:43:32
User entered '1'	Andrea Newlands (b) (4) (b) (4)	06 Apr 2021 12:43:32

US3412126

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:19

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:59
DataPoint Verified.	(b) (4)	21 Apr 2021 17:03:44
User closed query 'Please consider changing to 22 Aug 2020 since subject was in ER on 22 Aug 2020 - as we discussed' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 17:03:31
Query 'Please consider changing to 22 Aug 2020 since subject was in ER on 22 Aug 2020 - as we discussed' answered with 'this has been updated to 22-aug-20' (Site from CRA).	Steven Anderson (b) (4)	21 Apr 2021 15:44:23
Signature has been broken.	(b) (4)	
User entered '22 Aug 2020' reason for change: Data Entry Error	Steven Anderson (b) (4)	21 Apr 2021 15:43:44
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 14:47:11
User opened query 'Please consider changing to 22 Aug 2020 since subject was in ER on 22 Aug 2020 - as we discussed' (Site from CRA).		21 Apr 2021 14:47:09
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered '23 Aug 2020' reason for change: Data Entry Error	Andrea Newlands (b) (4)	06 Apr 2021 12:49:02
User entered empty.	(b) (4)	
	Andrea Newlands (b) (4)	06 Apr 2021 12:43:32
	(b) (4)	

US3412126

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:19

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered '01 Sep 2020' reason for change: Data Entry Error	Andrea Newlands (b) (4)	06 Apr 2021 12:49:02
User entered empty.	Andrea Newlands (b) (4)	06 Apr 2021 12:43:32

US3412126

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered 'No (N)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	06 Apr 2021 12:49:02
User entered empty.	(b) (4) Andrea Newlands (b) (4)	06 Apr 2021 12:43:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered empty.	Andrea Newlands (b) (4) (b) (4)	06 Apr 2021 12:43:32

US3412126

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered '0'	Andrea Newlands (b) (4) (b) (4)	06 Apr 2021 12:43:32

US3412126

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered '0'	Andrea Newlands (b) (4) (b) (4)	06 Apr 2021 12:43:32

US3412126

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered '0'	Andrea Newlands (b) (4) (b) (4)	06 Apr 2021 12:43:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered 'Not Related (NOT RELATED)'	Andrea Newlands (b) (4) (b) (4)	06 Apr 2021 12:43:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered 'Not Related (NOT RELATED)'	Andrea Newlands (b) (4) (b) (4)	06 Apr 2021 12:43:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:19

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:05:49
User closed query 'PV Query: Action taken with study drug in response to pneumonia was reported as none. Please consider updating action taken with study drug from none to withdrawn.' (Site from Safety).		19 Apr 2021 18:35:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:01
Query 'PV Query: Action taken with study drug in response to pneumonia was reported as none. Please consider updating action taken with study drug from none to withdrawn.' answered with 'updated' (Site from Safety).	(b) (4)	
	Andrea Newlands (b) (4)	16 Apr 2021 15:11:01
	(b) (4)	
DataPoint Un-verified.	Andrea Newlands (b) (4)	16 Apr 2021 15:10:53
	(b) (4)	
Signature has been broken.	Andrea Newlands (b) (4)	16 Apr 2021 15:10:53
	(b) (4)	
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	16 Apr 2021 15:10:53
	(b) (4)	
User opened query 'PV Query: Action taken with study drug in response to pneumonia was reported as none. Please consider updating action taken with study drug from none to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 21:13:54
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered 'None (NONE)'	Andrea Newlands (b) (4)	06 Apr 2021 12:43:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:19

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered '0'	Andrea Newlands (b) (4) (b) (4)	06 Apr 2021 12:43:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered '1'	Andrea Newlands (b) (4) (b) (4)	06 Apr 2021 12:43:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered '1'	Andrea Newlands (b) (4) (b) (4)	06 Apr 2021 12:43:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:19

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Andrea Newlands (b) (4) (b) (4)	06 Apr 2021 12:43:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:19

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51
User entered empty.	Andrea Newlands (b) (4) (b) (4)	06 Apr 2021 12:43:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:19

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:05:51

US3412126

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:19

[Narrative](#)

Audit	User	Time (GMT)
User entered (b) (6) FEMALE WITH CHEST PAIN. PT HAS SEVERE, SHARP PAIN, WORSE WITH COUGHING. PAIN LOCATED ON RIGHT SIDE. PT HAD PAIN STARTING THE FOLLOWING DAY. FELT LIKE SHE HAD A BROKEN RIB. SHE IS A SMOKER. ASSOCIATED SYMPTOMS INCLUDE POOR APPETITE, DYSPNEA. PATIENT WAS FOUND TO HAVE CAVITARY PNA. NOW S/P BRONCH. ID ON BOARD FOR ABX MANAGMENT. PLAN FOR LONG TERM IV ABX AT HOME (ZOSYN) FOR AN ADDITIONAL 3 WEEKS. CRX WITH STABLE EXTENSIVE R MIDDLE LOBE INFILTRATE/ CONSOLIDATION WITH KNOWN INTRAPARENCHYMAL ABSCESS. INITIAL LABS SHOWED LEUCOCYTOSIS, BLOOD CX SO FAR NGTD. CT SHOWED MULTIFOCAL CONSOLIDATION AND FLUID IN THE RML CONCERNING FOR ABSCESS. SEEN BY PULMONOLOGY, UNDERWENT BRONCHOSCOPY WITH BAL ON 8/25/20. BAL CULTURES AND CYTOLOGY PENDING ID WAS CONSULTED FOR ANTIBIOTIC MANAGEMENT. CULTURE RESULTS STAPHYLOCOCCUS AUREUS WAS NOT DETECTED STREP PNEUMO ANTIGEN WAS NOT DETECTED LEGIONELLA ANTIGEN URINE WAS NOT DETCTED LOWER REPIRATORY CULTURE NO WBC'S SEEN AND NO ORGANISMS SEEN. RESP VIRUS RSP FAC SOURCE = BAL INFLUENZA A-DFA NEGATIVE INFLUENZA B-DFA NEGATIVE PARAINFLUENZA 1- DFA NEGATIVE PARAINFLUENZA 2-DFA NEGATIVE PARAINFLUENZA 3- DFA NEGATIVE ADENOVIRUS- DFA NEGATIVE RSV-DFA NEGATIVE HUMAN METAPNEUMOVIRUS - DFA NEGATIVE FUNGUS CULTURE POSITIVE GROWTH SPARSE GROWTH OF YEAST,	Andrea Newlands (b) (4) (b) (4)	(b) (4) 06 Apr 2021 12:49:02

US3412126

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:19

[Narrative](#)

Audit	User	Time (GMT)
<p>SUSPECT CANDIDA SPECIES, POSSIBLE REPARATORY TRACT COLON
OVERVIEW: SUBJECT WAS ADMITTED FROM 8/23/20 - 9/01/2020 IN WHICH SHE PRESENTED FOR EVALUATION OF A DRY COUGH AND CHEST/RIB PAIN. THE SYMPTOMS WERE DESCRIBED AS ONGOING AND PROGRESSIVELY WORSENING, CHEST IMAGING WAS OBTAINED AND REVEALED MULTIFOCAL CONSOLIDATION AND FLUID IN THE RIGHT MIDDLE LOBE CONCERNING FOR AN ABSCESS, INFECTIOUS DISEASE WAS CONSULTED FOR ANTIBIOTIC MANAGEMENT. SHE WAS MEDICALLY CLEARED FOR DISCHARGE ON 9/1/20AND RECEIVED IV ZOSYN UNTIL 9/22/20. AS OF 9/10/20 SUBJECT DID NOT REPORT ANY FEVER, CHILLS, NAUSEA, VOMITING, OR DIARRHEA. SUBJECT HAS FOLLOW UPS THAT HAVE CAME BACK WITHOUT CONCERN'</p> <p>reason for change: Data Entry Error User entered empty.</p>	<p>Andrea Newlands (b) (4)</p>	<p>06 Apr 2021 12:43:32 (b) (4)</p>

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:19

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 12:43:32

US3412126

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:19

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 12:43:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:34:19

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Apr 2021 12:49:02

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:34:19

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:31
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:04
User closed query 'Solumedrol noted in PI medical record review and flagged in medical records - please review and update as appropriate' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 15:31:23
Query 'Solumedrol noted in PI medical record review and flagged in medical records - please review and update as appropriate' answered with 'solumedrol has been added' (Site from CRA).	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 21:00:41
User opened query 'Solumedrol noted in PI medical record review and flagged in medical records - please review and update as appropriate' (Site from CRA).	(b) (4), (b) (6)	13 Mar 2021 18:41:30
User closed query 'Solumedrol not added to OnMeds? Please review and update accordingly' (Site from CRA).	(b) (4), (b) (6)	13 Mar 2021 18:41:30
Query 'Solumedrol not added to OnMeds? Please review and update accordingly' answered with 'PER SUBI COULD NOT FIND IN SOURCE TO ADD SOLUMEDROL' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	11 Jan 2021 18:51:55
User closed query 'Subject received Rocephrin (p. 13), Azithromycin (p. 13), Zofran (pp. 24- 25) and morphine (p. 24-25) per hospital records? Please confirm and update accordingly' (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 21:16:32
User opened query 'Solumedrol not added to OnMeds? Please review and update accordingly' (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 21:15:25
User closed query 'hospital records mention Solumedrol and lovenox -please confirm not given or add to Con Meds if appropriate' (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 21:15:25
Query 'hospital records mention Solumedrol and lovenox -please confirm not given or add to Con Meds if appropriate' answered with 'CONFIRMED AND ADDED TO ' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:59:12
Query 'Subject received Rocephrin (p. 13), Azithromycin (p. 13), Zofran (pp. 24- 25) and morphine (p. 24-25) per hospital records? Please confirm and update accordingly' answered with 'CONFIRMED AND ADDED TO CON MEDS' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:58:26

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:34:19

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM re-query: Site response indicates updated; However there is no medication recorded for the corresponding dates. Please review, reconcile Diary Dose 1 and Concomitant Medication page and update as appropriate. Else provide explanation in query response.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 15:58:26
User opened query 'Subject received Rocephrin (p. 13), Azithromycin (p. 13), Zofran (pp. 24- 25) and morphine (p. 24-25) per hospital records? Please confirm and update accordingly' (Site from CRA).		04 Nov 2020 18:36:02
User opened query 'hospital records mention Solumedrol and lovenox -please confirm not given or add to Con Meds if appropriate' (Site from CRA).		04 Nov 2020 18:33:03
Query 'please check hospital records and confirm not given or add to Con Meds' canceled (Site from CRA)		04 Nov 2020 18:32:04
DataPoint Verified.		04 Nov 2020 18:31:55
User opened query 'please check hospital records and confirm not given or add to Con Meds' (Site from CRA).		04 Nov 2020 18:31:36
User closed query 'hospital records mention Solumedrol and lovenox -please confirm if were given and add to Con Meds if appropriate' (Site from CRA).		04 Nov 2020 18:31:36
Query 'Per CDM re-query: Site response indicates updated; However there is no medication recorded for the corresponding dates. Please review, reconcile Diary Dose 1 and Concomitant Medication page and update as appropriate. Else provide explanation in query response.' answered with 'please see entry line 15 in con meds.' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	27 Oct 2020 18:36:41
User closed query 'Per CDM: Diary Dose 1, Log Line #3, #4, #5, and #8 ed diary reports medication was taken for PAIN or FEVER, however there is no corresponding medication recorded. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 12:20:23

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
User opened query 'Per CDM re-query: Site response indicates updated; However there is no medication recorded for the corresponding dates. Please review, reconcile Diary Dose 1 and Concomitant Medication page and update as appropriate. Else provide explanation in query response.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 12:20:00
Query 'Per CDM: Diary Dose 1, Log Line #3, #4, #5, and #8 ed diary reports medication was taken for PAIN or FEVER, however there is no corresponding medication recorded. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number.' answered with 'updated.' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	20 Oct 2020 15:29:04
Query 'hospital records mention Solumedrol and lovenox -please confirm if were given and add to Con Meds if appropriate' answered with 'solumedrol and lovenox were not reported on source documents.' (Site from CRA).	Jacob sekinger (b) (4) (b) (4)	20 Oct 2020 15:21:42
User opened query 'Per CDM: Diary Dose 1, Log Line #3, #4, #5, and #8 ed diary reports medication was taken for PAIN or FEVER, however there is no corresponding medication recorded. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 05:00:23
User opened query 'hospital records mention Solumedrol and lovenox -please confirm if were given and add to Con Meds if appropriate' (Site from CRA).	(b) (4), (b) (6)	07 Oct 2020 18:17:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:30:44
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 14:39:54

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN W/OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 15:23:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 15:23:43
Data point term sent to Coder	System	21 Sep 2020 14:39:28
User entered 'oxycodone-acetaminophen'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:38:28

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	21 Sep 2020 14:38:28
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'osteoarthritis'	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:38:28

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered '5/325' reason for change: Data Entry Error	Melissa Fuson (b) (4)	20 Nov 2020 19:11:36
	(b) (4)	
User entered '7.5/325'	Mylene Asmar-Rios	21 Sep 2020 14:38:28
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered 'mg (mg)'	Mylene Asmar-Rios	21 Sep 2020 14:38:28
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	21 Sep 2020 14:38:28
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'as needed (PRN)'	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:38:28

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:19

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	21 Sep 2020 14:38:28
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	21 Sep 2020 14:38:28
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	21 Sep 2020 14:38:28
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered 'un UNK 2015'	Mylene Asmar-Rios	21 Sep 2020 14:38:28
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:19

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	21 Sep 2020 14:38:28
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	21 Sep 2020 14:38:28
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	21 Sep 2020 14:38:28
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	21 Sep 2020 14:38:28
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 14:38:28

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 14:38:28

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 14:38:28

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:16:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
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: CARTIA [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Sep 2020 14:40:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Sep 2020 14:40:45
Data point term sent to Coder User entered 'cartia'	System Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:40:31 21 Sep 2020 14:39:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:16:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'No (N)'	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:39:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:16:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'hypertension'	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:39:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:16:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered '300'	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:39:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:16:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'mg (mg)'	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:39:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:16:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered empty.	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:39:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:16:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'once daily (QD)'	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:39:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:19

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:16:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered empty.	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:39:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:16:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'Oral (ORAL)'	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:39:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:16:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered empty.	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:39:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:16:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'un UNK 2015'	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:39:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:19

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:16:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered '0'	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:39:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:16:28
User signature succeeded.	Richard Powell (b) (4) (b) (4)	16 Apr 2021 13:30:25
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 19:16:46
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:39:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:16:28
User signature succeeded.	Richard Powell (b) (4) (b) (4)	16 Apr 2021 13:30:25
User entered '01 Sep 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 19:16:46
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:39:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:16:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'No (N)'	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:39:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:16:28
User entered '1'	System	21 Sep 2020 14:39:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:16:28
User entered '1'	System	21 Sep 2020 14:39:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:16:28
User entered '804 (804)'	System	21 Sep 2020 14:39:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: CITALOPRAM HYDROBROMIDE, PRODUCTSYNONYM: CELEXA [CITALOPRAM HYDROBROMIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	21 Sep 2020 14:40:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 14:40:46
Data point term sent to Coder	System	21 Sep 2020 14:40:32
User entered 'celexa'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:40:31

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	21 Sep 2020 14:40:31
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered 'anxiety'	Mylene Asmar-Rios	21 Sep 2020 14:40:31
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered '40'	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:40:31

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered 'mg (mg)'	Mylene Asmar-Rios	21 Sep 2020 14:40:31
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	21 Sep 2020 14:40:31
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'once daily (QD)'	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:40:31

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:19

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	21 Sep 2020 14:40:31
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'Oral (ORAL)'	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:40:31

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	21 Sep 2020 14:40:31
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 04:20:30
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' answered with 'REVIEWED AND UPDATED START DATE TO 2015' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 18:14:57
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:27:55
User entered 'un UNK 2015'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:40:31

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:19

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	21 Sep 2020 14:40:31
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	21 Sep 2020 14:40:31
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	21 Sep 2020 14:40:31
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	21 Sep 2020 14:40:31
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 14:40:31

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 14:40:31

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 14:40:31

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Sep 2020 14:43:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 14:43:41
Data point term sent to Coder	System	21 Sep 2020 14:42:33
User entered 'diclofenac'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'No (N)'	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'osteoarthritis'	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered '75'	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'mg (mg)'	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	21 Sep 2020 14:41:57
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'twice daily (BID)'	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:19

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	21 Sep 2020 14:41:57
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'Oral (ORAL)'	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	21 Sep 2020 14:41:57
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered 'un UNK 2015'	Mylene Asmar-Rios	21 Sep 2020 14:41:57
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:19

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	21 Sep 2020 14:41:57
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'Yes (Y)'	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	21 Sep 2020 14:41:57
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'No (N)'	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Sep 2020 14:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 14:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 14:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:19

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Sep 2020 14:45:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 14:45:35
Data point term sent to Coder	System	21 Sep 2020 14:43:37
User entered 'furosemide'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:42:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	21 Sep 2020 14:42:45
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'hypertension'	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:42:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered '40'	Mylene Asmar-Rios	21 Sep 2020 14:42:45
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered 'mg (mg)'	Mylene Asmar-Rios	21 Sep 2020 14:42:45
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	21 Sep 2020 14:42:45
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'once daily (QD)'	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:42:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:19

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	21 Sep 2020 14:42:45
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	21 Sep 2020 14:42:45
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	21 Sep 2020 14:42:45
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered 'un UNK 2015'	Mylene Asmar-Rios	21 Sep 2020 14:42:45
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:19

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	21 Sep 2020 14:42:45
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	21 Sep 2020 14:42:45
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	21 Sep 2020 14:42:45
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	21 Sep 2020 14:42:45
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 14:42:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 14:42:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 14:42:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	21 Sep 2020 14:57:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Sep 2020 14:57:43
Data point term sent to Coder	System	21 Sep 2020 14:57:10
User entered 'potassium chloride'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:56:44

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	20 Nov 2020 19:19:18
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	21 Sep 2020 14:56:44
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'general health'	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:56:44

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered '10'	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:56:44

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:24:53
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'Updated to mEq per hospital records source' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	11 Jan 2021 18:44:25
User entered 'Other (OTHER)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	11 Jan 2021 18:43:58
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 05:53:33
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:56:44

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered 'mEq' reason for change: Data Entry Error	Melissa Fuson (b) (4)	11 Jan 2021 18:43:58
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	21 Sep 2020 14:56:44
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'twice daily (BID)'	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:56:44

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:19

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	21 Sep 2020 14:56:44
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'Oral (ORAL)'	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:56:44

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	21 Sep 2020 14:56:44
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered 'un UNK 2016'	Mylene Asmar-Rios	21 Sep 2020 14:56:44
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:19

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	21 Sep 2020 14:56:44
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	21 Sep 2020 14:56:44
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	21 Sep 2020 14:56:44
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	21 Sep 2020 14:56:44
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Sep 2020 14:56:44

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 14:56:44

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 14:56:44

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:19

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: TIZANIDINE HYDROCHLORIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Sep 2020 15:14:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 15:14:44
Data point term sent to Coder	System	21 Sep 2020 14:58:12
User entered 'tizanidine hydrochloride'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:57:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'No (N)'	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:57:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered 'osteoarthritis'	Mylene Asmar-Rios	21 Sep 2020 14:57:41
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered '4'	Mylene Asmar-Rios	21 Sep 2020 14:57:41
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered 'mg (mg)'	Mylene Asmar-Rios	21 Sep 2020 14:57:41
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	21 Sep 2020 14:57:41
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'three times daily (TID)'	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:57:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:19

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	21 Sep 2020 14:57:41
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'Oral (ORAL)'	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:57:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	21 Sep 2020 14:57:41
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User closed query 'Per DM CLR-RQ: Response noted. however, there was no update made on corresponding MH condition. Review CM start dates as this prior to the start of the corresponding MH condition. Review and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 04:21:33
Query 'Per DM CLR-RQ: Response noted. however, there was no update made on corresponding MH condition. Review CM start dates as this prior to the start of the corresponding MH condition. Review and update as appropriate.' answered with 'PER SOURCE HAS OSTEOARTHRITIS: HIPS IN 2010' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 14:37:35
User opened query 'Per DM CLR-RQ: Response noted. however, there was no update made on corresponding MH condition. Review CM start dates as this prior to the start of the corresponding MH condition. Review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Nov 2020 13:45:50
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 04:32:06
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' answered with 'UPDATED START DATE PER MEDICAL HISTORY TO 2010' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 18:15:52
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:29:58
User entered 'un UNK 2010'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:57:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:19

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	21 Sep 2020 14:57:41
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	21 Sep 2020 14:57:41
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	21 Sep 2020 14:57:41
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	21 Sep 2020 14:57:41
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	21 Sep 2020 14:57:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 14:57:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 14:57:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:19

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM CHLORIDE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	11 Jan 2021 19:04:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Jan 2021 19:04:40
Data point term sent to Coder	System	11 Jan 2021 18:24:15
Coding entries removed.	Melissa Fuson (b) (4)	11 Jan 2021 18:24:14
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM CHLORIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Nov 2020 10:08:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Nov 2020 10:08:16
Data point term sent to Coder	System	20 Nov 2020 19:20:51
Coding entries removed.	Melissa Fuson (b) (4)	20 Nov 2020 19:20:12
User entered 'CALCIUM CHLORIDE - 10%' reason for change: Data Entry Error	Melissa Fuson (b) (4)	20 Nov 2020 19:20:12
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM CHLORIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Oct 2020 22:31:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Oct 2020 22:31:34
Data point term sent to Coder	System	26 Oct 2020 17:19:18
Coding entries removed.	Melissa Fuson (b) (4)	26 Oct 2020 17:18:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM CHLORIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Sep 2020 00:47:56

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:19

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003. Data point term sent to Coder User entered 'calcium chloride'	Coder Import (b) (4) (b) (4) System Mylene Asmar-Rios (b) (4)	22 Sep 2020 00:47:56 21 Sep 2020 14:59:14 21 Sep 2020 14:58:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'No (N)'	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:58:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User closed query 'please correct - osteoporosis is correct spelling' (Site from CRA).	(b) (4) (b) (4), (b) (6)	13 Feb 2021 16:34:09
Query 'please correct - osteoporosis is correct spelling' answered with 'CORRECTED SPELLING' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	11 Jan 2021 18:26:02
User entered 'OSTEOPOROSIS' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	11 Jan 2021 18:24:14
User opened query 'please correct - osteoporosis is correct spelling' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 14:52:45
User closed query 'Please correct spelling' (Site from CRA).		29 Dec 2020 14:49:37
Query 'Please correct spelling' answered with 'CORRECTED SPELLING TO OSTEOPEROSIS' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 14:01:18
User opened query 'Please correct spelling' (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 21:18:17
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).		28 Oct 2020 04:31:01
User entered 'OSTEOPEROSIS' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:18:46
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'VERIFIED SOURCE AND ADDED OSTEOPOROSIS TO MEDICAL HISTORY' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:18:26
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:27:19
User entered 'osteoporosis'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:58:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered '500'	Mylene Asmar-Rios	21 Sep 2020 14:58:42
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered 'mg (mg)'	Mylene Asmar-Rios	21 Sep 2020 14:58:42
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	21 Sep 2020 14:58:42
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'once daily (QD)'	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:58:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:19

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	21 Sep 2020 14:58:42
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:25:29
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'ROUTE IS PO ON SOURCE' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	11 Jan 2021 18:25:52
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 05:53:46
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:58:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	21 Sep 2020 14:58:42
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User closed query 'Per CDM RQ: Please verify and reconcile the start date of the MH condition. Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:19:25
Query 'Per CDM RQ: Please verify and reconcile the start date of the MH condition. Thank you!' answered with 'please clarify as MH entry has already been updated to prior to the start of the conmed.' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	12 Apr 2021 17:00:06
User opened query 'Per CDM RQ: Please verify and reconcile the start date of the MH condition. Thank you!' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 13:00:21
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 13:00:21
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'mh start updated' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	05 Apr 2021 16:05:25
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 12:08:08
User entered 'un UNK 2014'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 14:58:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:19

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	21 Sep 2020 14:58:42
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	21 Sep 2020 14:58:42
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	21 Sep 2020 14:58:42
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	21 Sep 2020 14:58:42
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 14:58:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 14:58:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 14:58:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: OTHER DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, PRODUCT: DENOSUMAB, PRODUCTSYNONYM: PROLIA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Jan 2021 18:29:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Jan 2021 18:29:41
Data point term sent to Coder	System	11 Jan 2021 18:28:22
Data point term sent to Coder	System	11 Jan 2021 18:27:20
Coding entries removed.	Melissa Fuson (b) (4) (b) (4)	11 Jan 2021 18:26:40
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: OTHER DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, PRODUCT: DENOSUMAB, PRODUCTSYNONYM: PROLIA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 17:48:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 17:48:14
Data point term sent to Coder	System	26 Oct 2020 17:19:19
Coding entries removed.	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:19:10
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: OTHER DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, PRODUCT: DENOSUMAB, PRODUCTSYNONYM: PROLIA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 15:02:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:19

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003. Data point term sent to Coder User entered 'prolia'	Coder Import (b) (4) (b) (4) System Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:02:41 21 Sep 2020 15:02:20 21 Sep 2020 15:01:23

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'No (N)'	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:01:23

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User closed query 'please correct - osteoporosis is correct spelling' (Site from CRA).	(b) (4) (b) (4), (b) (6)	13 Feb 2021 16:34:22
Query 'please correct - osteoporosis is correct spelling' answered with 'CORRECTED SPELLING OF OSTEOPOROSIS' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	11 Jan 2021 18:27:07
User entered 'OSTEOPOROSIS' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	11 Jan 2021 18:26:40
User opened query 'please correct - osteoporosis is correct spelling' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 14:52:22
User closed query 'Please correct spelling' (Site from CRA).		29 Dec 2020 14:52:22
Query 'Please correct spelling' answered with 'CORRECTED SPELLING TO OSTEOPEROSIS' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 14:01:50
User opened query 'Please correct spelling' (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 21:18:23
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' canceled (Site from DM).		18 Nov 2020 20:05:13
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).		18 Nov 2020 20:04:52
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).		28 Oct 2020 04:18:36
User entered 'OSTEOPEROSIS' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:19:10

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:19

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'OSTEOPOROSIS WAS CROSSED OFF MEDICAL HISTORY ON 04-SUG-2020 VIA SOURCE' (Site from DM).	Melissa Fuson (b) (4)	26 Oct 2020 17:10:45
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:29:23
User entered 'osteoporosis'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:01:23

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered '60'	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:01:23

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'mg (mg)'	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:01:23

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	21 Sep 2020 15:01:23
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	(b) (4) System	01 Oct 2020 14:20:51
User entered 'other (OTHER)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	01 Oct 2020 14:20:51
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	21 Sep 2020 15:01:23
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:01:23

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:19

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered 'two times per year'	Mylene Asmar-Rios	21 Sep 2020 15:01:23
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:25:40
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'UPDATED TO SUBCUTANEOUS PER SOURCE OF CON MEDICATION RECORD' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	11 Jan 2021 18:28:43
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	11 Jan 2021 18:28:04
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 05:54:03
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:01:23

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	21 Sep 2020 15:01:23
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered 'UN UNK 2018' reason for change: Data Entry Error	Melissa Fuson (b) (4)	20 Nov 2020 19:22:52
	(b) (4)	
User entered 'UN UNK 2015' reason for change: Data Entry Error	Melissa Fuson (b) (4)	26 Oct 2020 17:17:44
	(b) (4)	
User entered 'un UNK 2018'	Mylene Asmar-Rios	21 Sep 2020 15:01:23
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:19

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	21 Sep 2020 15:01:23
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	26 Oct 2020 17:17:44
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	26 Oct 2020 17:09:53
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	21 Sep 2020 15:01:23
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4)	26 Oct 2020 17:17:44
	(b) (4)	
User entered '04 Aug 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4)	26 Oct 2020 17:09:53
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	21 Sep 2020 15:01:23
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	21 Sep 2020 15:01:23
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 14:20:51
User entered '1'	System	21 Sep 2020 15:01:23

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 14:20:51
User entered '1'	System	21 Sep 2020 15:01:23

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 14:20:51
User entered '804 (804)'	System	21 Sep 2020 15:01:23

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:16:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:49:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 12:21:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 12:21:39
Data point term sent to Coder	System	21 Sep 2020 15:02:20
User entered 'aspirin'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:02:17

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:16:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:49:05
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:02:17

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:16:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User closed query 'Per DM CLR: Please review AE eCRF's AE #1 UPPER RESPIRATORY INFECTION (Other Action Taken=NONE); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION. Please update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:26:22
Query 'Per DM CLR: Please review AE eCRF's AE #1 UPPER RESPIRATORY INFECTION (Other Action Taken=NONE); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION. Please update as appropriate.' answered with 'UPDATED OTHER ACTION TAKE TO CON MEDICATION' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	11 Jan 2021 18:31:56
User opened query 'Per DM CLR: Please review AE eCRF's AE #1 UPPER RESPIRATORY INFECTION (Other Action Taken=NONE); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION. Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 05:54:44
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:49:06
User entered 'uri'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:02:17

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:16:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:49:08
User entered '81'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:02:17

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:16:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:49:10
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:02:17

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:16:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:49:14
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:02:17

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:16:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:49:16
User entered 'as needed (PRN)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:02:17

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:19

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:16:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:49:17
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:02:17

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:16:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:49:19
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:02:17

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:16:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:49:21
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:02:17

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:16:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:49:25
User entered '05 Aug 2020'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:02:17

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:16:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:49:27
User entered '0'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:02:17

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:16:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:49:29
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4)	28 Oct 2020 04:19:29
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'RECORDED STOP DATE OF 18 AUG 2020' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:24:05
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:23:48
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:26:50
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:02:17

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:16:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:49:31
User entered '18 Aug 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4)	26 Oct 2020 17:23:48
User entered empty.	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:02:17

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:16:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:49:38
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:02:17

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:16:38
User entered empty.	System	21 Sep 2020 15:02:17

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:16:38
User entered empty.	System	21 Sep 2020 15:02:17

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:16:38
User entered empty.	System	21 Sep 2020 15:02:17

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:19

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	11 Jan 2021 19:08:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Jan 2021 19:08:42
Data point term sent to Coder	System	11 Jan 2021 18:33:25
Coding entries removed.	Melissa Fuson (b) (4)	11 Jan 2021 18:32:28
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 06:04:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 06:04:46
Data point term sent to Coder	System	20 Nov 2020 19:25:54
Coding entries removed.	Melissa Fuson (b) (4)	20 Nov 2020 19:25:36
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Sep 2020 15:06:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Sep 2020 15:06:45
Data point term sent to Coder	System	21 Sep 2020 15:05:32
User entered 'guaifenesin'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:04:40

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'No (N)'	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:04:40

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User closed query 'please spell out seasonal allergic rhinitis' (Site from CRA).	(b) (4) (b) (4), (b) (6)	13 Feb 2021 16:42:49
Query 'please spell out seasonal allergic rhinitis' answered with 'UPDATED SPELLING OUT OF SAR' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	11 Jan 2021 18:32:39
User entered 'ALLERGIC RHINITIS - SEASONAL' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	11 Jan 2021 18:32:28
User opened query 'please spell out seasonal allergic rhinitis' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 14:57:12
User entered 'SAR' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 19:25:36
User entered 'pneumonia'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:04:40

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 05:13:23
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' answered with 'this information has been updated per query' (Site from DM).	Steven Anderson (b) (4) (b) (4)	18 Feb 2021 15:00:46
User entered '100/5' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	18 Feb 2021 15:00:33
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 07:40:30
User entered '300'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:04:40

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered 'Other (OTHER)' reason for change: Data Entry Error	Steven Anderson (b) (4)	18 Feb 2021 15:00:33
	(b) (4)	
User entered 'mg (mg)'	Mylene Asmar-Rios	21 Sep 2020 15:04:40
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4) (b) (4)	16 Apr 2021 13:30:25
User entered 'mg/ml' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	18 Feb 2021 15:00:33
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:04:40

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'three times daily (TID)'	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:04:40

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:19

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	21 Sep 2020 15:04:40
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'Oral (ORAL)'	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:04:40

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	21 Sep 2020 15:04:40
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 13:52:46
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' answered with 'mh was updated' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	05 Apr 2021 16:06:28
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 11:35:29
User closed query 'Per DM CLR: After updating the indication to reflect the underlying medical condition this medication is being used to prevent/treat, and if the indication refers to ALLERGIC RHINITIS - SEASONAL, please note the Con Med start date is prior to the start date of this MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 05:14:34
Query 'Per DM CLR: After updating the indication to reflect the underlying medical condition this medication is being used to prevent/treat, and if the indication refers to ALLERGIC RHINITIS - SEASONAL, please note the Con Med start date is prior to the start date of this MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' answered with 'SAR date has been updated. subject believes she has been on this medication for around 3 years. Subject would not be on this medication without having history of SAR' (Site from DM).	Steven Anderson (b) (4) (b) (4)	18 Feb 2021 15:03:39

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: After updating the indication to reflect the underlying medical condition this medication is being used to prevent/treat, and if the indication refers to ALLERGIC RHINITIS - SEASONAL, please note the Con Med start date is prior to the start date of this MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 07:38:49
User entered 'UN UNK 2017' reason for change:	Melissa Fuson (b) (4)	20 Nov 2020 19:25:36
Data Entry Error	(b) (4)	
User entered '01 Sep 2020'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:04:40

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:19

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	21 Sep 2020 15:04:40
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	21 Sep 2020 15:04:40
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	21 Sep 2020 15:04:40
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'No (N)'	(b) (4) Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:04:40

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	21 Sep 2020 15:04:40

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 15:04:40

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 15:04:40

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN;TAZOBACTAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Jan 2021 21:13:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Jan 2021 21:13:44
Data point term sent to Coder	System	11 Jan 2021 18:35:25
Coding entries removed.	Melissa Fuson (b) (4)	11 Jan 2021 18:34:55
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:38:05
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN;TAZOBACTAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 15:22:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 15:22:45
Data point term sent to Coder	System	21 Sep 2020 15:08:38
User entered 'piperacillin-tazobactam'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:08:15

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:38:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:08:15

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 15:29:43
User closed query 'Per DM CLR: Other Action Taken = Concomitant Procedure, however there is also a Concomitant Medication recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 15:27:23
Query 'Per DM CLR: Other Action Taken = Concomitant Procedure, however there is also a Concomitant Medication recorded that matches this AE during this timeframe. Please review and update this field.' answered with 'UPDATED INDICATION TO REFLECT WAS TAKEN FOR AE OF PNEUMONIA' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	11 Jan 2021 18:36:07
DataPoint Un-verified.	Melissa Fuson (b) (4) (b) (4)	11 Jan 2021 18:34:55
User entered 'AE - PNEUMONIA' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	11 Jan 2021 18:34:55
User opened query 'Per DM CLR: Other Action Taken = Concomitant Procedure, however there is also a Concomitant Medication recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 06:12:22
Query 'Per DM CLR: Other Action Taken = Concomitant Procedure, however there is a Concomitant Medication recorded that matches this AE during this timeframe. Please review and update this field.' canceled (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 06:12:16
User opened query 'Per DM CLR: Other Action Taken = Concomitant Procedure, however there is a Concomitant Medication recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 06:11:32
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:38:09
User entered 'pneumonia'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:08:15

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:08:12
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' answered with 'per medical records this is the dosage level they gave. Medical records did not pertain to two separate dosage levels therefor would be impossible to tell unless updated by hospital. site will keep what medical records state until otherwise instructed' (Site from DM).	Steven Anderson (b) (4) (b) (4)	10 Feb 2021 17:06:13
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 09:38:43
DataPoint Verified.		04 Nov 2020 17:38:11
User entered '3.375'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:08:15

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:38:13
User entered 'g (g)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:08:15

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:38:34
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:08:15

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:58:46
DataPoint Un-verified.	Melissa Fuson (b) (4)	20 Nov 2020 19:14:29
User entered 'three times daily (TID)' reason for change: Data Entry Error	(b) (4) Melissa Fuson (b) (4)	20 Nov 2020 19:14:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:38:36
User entered 'other (OTHER)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:08:15

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:19

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 14:59:02
DataPoint Un-verified.	(b) (4), (b) (6)	29 Dec 2020 14:58:58
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 14:58:48
User closed query 'Per CDM: Three times daily is an available option in the drop down for frequency. Please review if the alternative is appropriate and consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 07:16:59
Query 'Per CDM: Three times daily is an available option in the drop down for frequency. Please review if the alternative is appropriate and consider updating the frequency to the available equivalent rather than Other. Thank you.' answered with 'UPDATED TO THREE TIMES DAILY - SOURCE HAS Q EVERY 8 HOURS' (Site from DM).	Melissa Fuson (b) (4)	20 Nov 2020 19:15:13
DataPoint Un-verified.	(b) (4)	20 Nov 2020 19:14:29
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4)	20 Nov 2020 19:14:29
User opened query 'Per CDM: Three times daily is an available option in the drop down for frequency. Please review if the alternative is appropriate and consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 14:04:07
Query 'Per CDM: Four times daily is an available option in the drop down for frequency. Please review if the alternative is appropriate and consider updating the frequency to the available equivalent rather than Other. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 14:04:00

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Four times daily is an available option in the drop down for frequency. Please review if the alternative is appropriate and consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 14:02:14
DataPoint Verified.		04 Nov 2020 17:38:38
User entered 'every 8 hours'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:08:15

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:38:40
User entered 'Intravenous (INTRAVENOUS)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:08:15

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:38:42
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:08:15

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 06:49:27
DataPoint Verified.		15 Mar 2021 21:26:31
User closed query 'Start date 26 Aug 2020? Please confirm and correct' (Site from CRA).		15 Mar 2021 21:26:28
Query 'Start date 26 Aug 2020? Please confirm and correct' answered with 'this is correct and has been updated per query' (Site from CRA).	Steven Anderson (b) (4)	15 Mar 2021 19:53:20
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, clarify.' answered with 'this has been updated' (Site from DM).	Steven Anderson (b) (4)	15 Mar 2021 19:53:08
User entered '26 Aug 2020' reason for change: Data Entry Error	Steven Anderson (b) (4)	15 Mar 2021 19:52:58
User entered '22 Sep 2020' reason for change: Data Entry Error	Steven Anderson (b) (4)	15 Mar 2021 19:52:40
User opened query 'Start date 26 Aug 2020? Please confirm and correct' (Site from CRA).	(b) (4), (b) (6)	13 Mar 2021 18:24:30
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, clarify.' (Site from DM).		01 Mar 2021 08:21:06
DataPoint Un-verified.	Melissa Fuson (b) (4)	11 Jan 2021 18:34:55
User entered '26 Apr 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4)	11 Jan 2021 18:34:55
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:38:47
User entered '01 Sep 2020'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:08:15

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:19

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:38:49
User entered '0'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:08:15

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 02:51:22
User closed query 'per source note completed on 22 Sep 2020 - please confirm and update accordingly' (Site from CRA).	(b) (4)	16 Nov 2020 02:51:20
Query 'per source note completed on 22 Sep 2020 - please confirm and update accordingly' answered with 'this has been updated' (Site from CRA).	Steven Anderson (b) (4)	10 Nov 2020 23:57:43
User entered 'No (N)' reason for change: Data Entry Error	Steven Anderson (b) (4)	10 Nov 2020 23:57:36
User opened query 'per source note completed on 22 Sep 2020 - please confirm and update accordingly' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 17:37:23
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:08:15

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 15:29:23
User closed query 'per medical records stop date = 22 Sep 2020? Please confirm and correct' (Site from CRA).	(b) (4)	19 Mar 2021 15:29:19
Query 'per medical records stop date = 22 Sep 2020? Please confirm and correct' answered with 'this is correct and has been updated per source' (Site from CRA).	Steven Anderson (b) (4)	15 Mar 2021 19:54:51
User closed query 'End date is prior to start date. Please correct.' (Site from System).	System	15 Mar 2021 19:52:58
User entered '22 Sep 2020' reason for change: Data Entry Error	Steven Anderson (b) (4)	15 Mar 2021 19:52:58
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	15 Mar 2021 19:52:40
User opened query 'per medical records stop date = 22 Sep 2020? Please confirm and correct' (Site from CRA).	(b) (4), (b) (6)	13 Mar 2021 18:24:59
DataPoint Un-verified.	(b) (4), (b) (6)	13 Mar 2021 18:15:53
DataPoint Verified.	(b) (4), (b) (6)	13 Feb 2021 16:43:12
User closed query 'please confirm stop date - per source 26 Aug 2020?' (Site from CRA).	(b) (4), (b) (6)	13 Feb 2021 16:43:07
Query 'please confirm stop date - per source 26 Aug 2020?' answered with 'UPDATED STOP DATE TO 26-AUG-2020 PER SOURCE' (Site from CRA).	Melissa Fuson (b) (4)	11 Jan 2021 18:37:32
DataPoint Un-verified.	(b) (4)	
	Melissa Fuson (b) (4)	11 Jan 2021 18:37:03
User entered '26 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Melissa Fuson (b) (4)	11 Jan 2021 18:37:03
User opened query 'please confirm stop date - per source 26 Aug 2020?' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 15:00:35
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 02:51:23
DataPoint Un-verified.	Steven Anderson (b) (4)	10 Nov 2020 23:57:36
	(b) (4)	
User entered '22 Sep 2020' reason for change: Data Entry Error	Steven Anderson (b) (4)	10 Nov 2020 23:57:36
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:36:30
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:08:15

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:36:28
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	21 Sep 2020 15:08:15

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:05
User entered '3'	System	20 Nov 2020 19:14:29
User entered empty.	System	21 Sep 2020 15:08:15

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:05
User entered '1'	System	20 Nov 2020 19:14:29
User entered empty.	System	21 Sep 2020 15:08:15

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:05
User entered '804 (804)'	System	20 Nov 2020 19:14:29
User entered empty.	System	21 Sep 2020 15:08:15

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:19

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:53
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OTHER COUGH SUPPRESSANTS, PRODUCT: BENZONATATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Nov 2020 09:30:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Nov 2020 09:30:16
Data point term sent to Coder	System	20 Nov 2020 19:38:35
Data point term sent to Coder	System	20 Nov 2020 19:35:30
Coding entries removed.	Melissa Fuson (b) (4)	20 Nov 2020 19:35:18
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:42:55
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OTHER COUGH SUPPRESSANTS, PRODUCT: BENZONATATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Oct 2020 22:55:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Oct 2020 22:55:24
Data point term sent to Coder	System	06 Oct 2020 19:24:21
Data point term sent to Coder	System	06 Oct 2020 19:22:04
User entered 'BENZONATATE'	Melissa Fuson (b) (4)	06 Oct 2020 19:21:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:53
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:42:56
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:21:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:53
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 21:12:48
User closed query 'please consider updating to URI as indicated in source' (Site from CRA).	(b) (4)	15 Dec 2020 21:12:44
User closed query 'Per CDM re-query: Thank you for the response. For the recorded AE, 'UPPER RESPIRATORY INFECTION', Other action taken = none. Please review if it should be changed to 'Concomitant Medication'. Please review, reconcile and update accordingly.' (Site from DM).	(b) (4)	15 Dec 2020 04:27:24
Query 'Per CDM re-query: Thank you for the response. For the recorded AE, 'UPPER RESPIRATORY INFECTION', Other action taken = none. Please review if it should be changed to 'Concomitant Medication'. Please review, reconcile and update accordingly.' answered with 'UPDATED AE TO YES FOR CON MED' (Site from DM).	Melissa Fuson (b) (4)	14 Dec 2020 14:45:37
User opened query 'Per CDM re-query: Thank you for the response. For the recorded AE, 'UPPER RESPIRATORY INFECTION', Other action taken = none. Please review if it should be changed to 'Concomitant Medication'. Please review, reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 07:58:19
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 07:27:21
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'UPDATED TO URI PER AE STARTING ON 05-AUG-2020 AND ENDING ON 18-AUG-2020' (Site from DM).	Melissa Fuson (b) (4)	20 Nov 2020 19:37:59
User entered 'URI - UPPER RESPIRATORY INFECTION' reason for change: Data Entry Error	Melissa Fuson (b) (4)	20 Nov 2020 19:37:39

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:19

[Indication](#)

Audit	User	Time (GMT)
Query 'please consider updating to URI as indicated in source' answered with 'UPDATED TO URI PER AE STARTING ON 05-AUG-2020 AND ENDING ON 18-AUG-2020' (Site from CRA).	Melissa Fuson (b) (4)	20 Nov 2020 19:36:18
User entered 'URI' reason for change: Data Entry Error	(b) (4)	
User entered 'URI' reason for change: Data Entry Error	Melissa Fuson (b) (4)	20 Nov 2020 19:35:18
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 20:04:24
User opened query 'please consider updating to URI as indicated in source' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 17:44:04
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 17:43:08
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:42:58
User entered 'ONGOING MILD INTERMITTENT COUGH' reason for change: Data Entry Error	Melissa Fuson (b) (4)	06 Oct 2020 19:23:22
User entered 'URNIARY TRACT INFECTION FOR AE EVENT'	Melissa Fuson (b) (4)	06 Oct 2020 19:21:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:53
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:43:00
User entered '200'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:21:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:53
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:43:02
User entered 'mg (mg)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:21:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:53
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:43:10
User entered empty.	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:21:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:53
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:43:13
User entered 'three times daily (TID)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:21:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:19

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:53
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:43:20
User entered empty.	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:21:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:53
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:43:24
User entered 'Oral (ORAL)'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:21:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:53
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:43:26
User entered empty.	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:21:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:53
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:43:28
User entered '14 Aug 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4)	06 Oct 2020 19:23:22
User entered '05 Aug 2020'	(b) (4) Melissa Fuson (b) (4)	06 Oct 2020 19:21:41
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:53
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:43:29
User entered '0'	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:21:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:53
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:43:31
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	06 Oct 2020 19:32:40
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	06 Oct 2020 19:23:31
User entered 'No (N)'	Melissa Fuson (b) (4)	06 Oct 2020 19:21:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:53
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:43:33
User entered '18 Aug 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:32:40
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	06 Oct 2020 19:23:31
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	06 Oct 2020 19:23:22
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:23:22
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Oct 2020 19:22:06
User entered '18 Aug 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:22:06
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Oct 2020 19:21:41
User entered '18 Aug ' (non-conformant).	Melissa Fuson (b) (4) (b) (4)	06 Oct 2020 19:21:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:53
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:02:27
User closed query 'Per CDM re-query: Thank you for the response. However, please note the indication recorded doesn't reflect the solicited event criteria as per protocol. Please review the response for this field and update to 'No' as appropriate else clarify. Thank you.' (Site from DM).	(b) (4)	15 Dec 2020 04:28:20
Query 'Per CDM re-query: Thank you for the response. However, please note the indication recorded doesn't reflect the solicited event criteria as per protocol. Please review the response for this field and update to 'No' as appropriate else clarify. Thank you.' answered with 'UPDATED SOLICITED EVENT TO NO' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 14:46:47
DataPoint Un-verified.	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 14:46:03
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	14 Dec 2020 14:46:03
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 07:30:27
User opened query 'Per CDM re-query: Thank you for the response. However, please note the indication recorded doesn't reflect the solicited event criteria as per protocol. Please review the response for this field and update to 'No' as appropriate else clarify. Thank you.' (Site from DM).	(b) (4)	27 Nov 2020 07:30:25

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:19

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification.' answered with 'UPDATED TO URI PER AE STARTING ON 05-AUG-2020 AND ENDING ON 18-AUG-2020' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 19:38:40
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:04:35
User entered 'Yes (Y)'	(b) (4), (b) (6) Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 17:43:35 06 Oct 2020 19:21:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:53
User entered '3'	System	06 Oct 2020 19:21:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:53
User entered '1'	System	06 Oct 2020 19:21:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:53
User entered '804 (804)'	System	06 Oct 2020 19:21:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:19

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Jan 2021 19:02:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Jan 2021 19:02:41
Data point term sent to Coder Coding entries removed.	System	11 Jan 2021 18:47:33
	Melissa Fuson (b) (4)	11 Jan 2021 18:46:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Oct 2020 15:29:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Oct 2020 15:29:38
Data point term sent to Coder	System	20 Oct 2020 15:28:51
User entered 'aspirin'	Jacob sekinger (b) (4)	20 Oct 2020 15:28:33

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'No (N)'	(b) (4) Jacob sekinger (b) (4)	20 Oct 2020 15:28:33
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User closed query 'Per DM CLR: Please note that there is no AE or Diary event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:27:45
Query 'Per DM CLR: Please note that there is no AE or Diary event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf.' answered with 'ASPIRIN WAS TAKEN FOR URI AE FOR FEVER. UPDATED SOURCE' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	11 Jan 2021 18:47:35
User entered 'FEVER FOR URI' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	11 Jan 2021 18:46:42
User opened query 'Per DM CLR: Please note that there is no AE or Diary event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 06:12:50
User entered 'fever'	Jacob sekinger (b) (4) (b) (4)	20 Oct 2020 15:28:33

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered '81'	Jacob sekinger (b) (4)	20 Oct 2020 15:28:33

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'mg (mg)'	(b) (4) Jacob sekinger (b) (4) (b) (4)	20 Oct 2020 15:28:33

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered empty.	(b) (4) Jacob sekinger (b) (4)	20 Oct 2020 15:28:33
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'as needed (PRN)'	(b) (4) Jacob sekinger (b) (4)	20 Oct 2020 15:28:33
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:19

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered empty.	(b) (4) Jacob sekinger (b) (4) (b) (4)	20 Oct 2020 15:28:33

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'Oral (ORAL)'	(b) (4) Jacob sekinger (b) (4)	20 Oct 2020 15:28:33
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered empty.	(b) (4) Jacob sekinger (b) (4) (b) (4)	20 Oct 2020 15:28:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:58
User signature succeeded.	Richard Powell (b) (4) (b) (4)	16 Apr 2021 13:30:25
User entered '08 Aug 2020' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	05 Apr 2021 16:10:44
User entered '25 Aug 2020'	Jacob sekinger (b) (4) (b) (4)	20 Oct 2020 15:28:33

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:19

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered '0'	(b) (4) Jacob sekinger (b) (4) (b) (4)	20 Oct 2020 15:28:33

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User closed query 'Per DM CLR: Con Med start date is after the end date of the corresponding AE. Please review and reconcile Con Med and AE start/end dates as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:05:32
Query 'Per DM CLR: Con Med start date is after the end date of the corresponding AE. Please review and reconcile Con Med and AE start/end dates as appropriate. ' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	05 Apr 2021 16:11:17
User entered 'No (N)' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	05 Apr 2021 16:11:04
User opened query 'Per DM CLR: Con Med start date is after the end date of the corresponding AE. Please review and reconcile Con Med and AE start/end dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 11:45:52
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	20 Oct 2020 15:28:33

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User closed query 'End date is prior to start date. Please correct.' (Site from System).	(b) (4)	05 Apr 2021 16:11:21
User entered '18 Aug 2020' reason for change: Data Entry Error	System	05 Apr 2021 16:11:21
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	Andrea Newlands (b) (4)	05 Apr 2021 16:11:04
User opened query 'End date is prior to start date. Please correct.' (Site from System).	(b) (4)	05 Apr 2021 16:11:04
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	05 Apr 2021 16:10:44
User entered '18 Apr 2020' reason for change: Data Entry Error	System	05 Apr 2021 16:10:44
User entered empty.	Andrea Newlands (b) (4)	05 Apr 2021 16:10:44
	(b) (4)	
	Jacob sekinger (b) (4)	20 Oct 2020 15:28:33
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'No (N)'	(b) (4) Jacob sekinger (b) (4) (b) (4)	20 Oct 2020 15:28:33

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:58
User entered empty.	System	20 Oct 2020 15:28:33

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:58
User entered empty.	System	20 Oct 2020 15:28:33

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:20:58
User entered empty.	System	20 Oct 2020 15:28:33

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:34:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: TRIAMCINOLONE ACETONIDE, PRODUCTSYNONYM: NASACORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 05:27:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 05:27:34
Data point term sent to Coder	System	26 Oct 2020 17:28:43
User entered 'NASACORT - 55MCG'	Melissa Fuson (b) (4)	26 Oct 2020 17:27:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:34:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:27:42
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:34:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'SEASONAL ALLERGIES'	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:27:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:34:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered '55'	Melissa Fuson (b) (4)	26 Oct 2020 17:27:42
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:34:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered 'ug (ug)'	Melissa Fuson (b) (4)	26 Oct 2020 17:27:42
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:34:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	26 Oct 2020 17:27:42
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:34:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered 'twice daily (BID)'	Melissa Fuson (b) (4)	26 Oct 2020 17:27:42
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:34:19

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	26 Oct 2020 17:27:42
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:34:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'Nasal (NASAL)'	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:27:42
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:34:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	26 Oct 2020 17:27:42
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:34:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered '08 Oct 2019' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 17:30:54
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	Melissa Fuson (b) (4)	26 Oct 2020 17:28:23
User entered '08 Oct 1999' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 17:28:23
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	26 Oct 2020 17:27:42
User entered empty.	Melissa Fuson (b) (4)	26 Oct 2020 17:27:42
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:34:19

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered '0'	Melissa Fuson (b) (4)	26 Oct 2020 17:27:42
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:34:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 17:28:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 17:28:23
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	26 Oct 2020 17:28:23
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 17:27:42
User entered empty.	Melissa Fuson (b) (4)	26 Oct 2020 17:27:42
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:34:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4)	26 Oct 2020 17:28:23
	(b) (4)	
User entered '8 Oct 2019'	Melissa Fuson (b) (4)	26 Oct 2020 17:27:42
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:34:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered 'No (N)'	Melissa Fuson (b) (4)	26 Oct 2020 17:27:42
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:34:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	26 Oct 2020 17:27:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Oct 2020 17:27:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Oct 2020 17:27:42

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:34:19

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: MOMETASONE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	27 Oct 2020 05:31:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 05:31:34
Data point term sent to Coder	System	26 Oct 2020 17:30:45
User entered 'MOMETASONE - 50MCG'	Melissa Fuson (b) (4) (b) (4)	26 Oct 2020 17:30:16

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:34:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered 'No (N)'	Melissa Fuson (b) (4)	26 Oct 2020 17:30:16
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:34:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'SEASONAL ALLERGIES'	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:30:16

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:34:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered '50'	Melissa Fuson (b) (4)	26 Oct 2020 17:30:16
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:34:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered 'ug (ug)'	Melissa Fuson (b) (4)	26 Oct 2020 17:30:16
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:34:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	26 Oct 2020 17:30:16
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:34:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered 'twice daily (BID)'	Melissa Fuson (b) (4)	26 Oct 2020 17:30:16
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:34:19

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	26 Oct 2020 17:30:16
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:34:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'Nasal (NASAL)'	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:30:16
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:34:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	26 Oct 2020 17:30:16
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:34:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered '20 Aug 2019'	Melissa Fuson (b) (4)	26 Oct 2020 17:30:16
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:34:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered '0'	Melissa Fuson (b) (4)	26 Oct 2020 17:30:16
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:34:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'Yes (Y)'	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:30:16
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:34:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	26 Oct 2020 17:30:16
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:34:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4)	26 Oct 2020 17:30:16
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:34:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	26 Oct 2020 17:30:16

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Oct 2020 17:30:16

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Oct 2020 17:30:16

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:34:19

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Jan 2021 21:09:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Jan 2021 21:09:54
Data point term sent to Coder	System	11 Jan 2021 18:41:32
Coding entries removed.	Melissa Fuson (b) (4) (b) (4)	11 Jan 2021 18:41:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 03:38:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 03:38:54
Data point term sent to Coder	System	19 Nov 2020 20:42:59
User entered 'morphine'	Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 20:42:09

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:34:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'No (N)'	(b) (4) Jacob sekinger (b) (4)	19 Nov 2020 20:42:09
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:34:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User closed query 'please specify type of pain' (Site from CRA).	(b) (4) (b) (4), (b) (6)	13 Feb 2021 16:46:13
Query 'please specify type of pain' answered with 'UPDATED TO RIB PAIN' (Site from CRA).	Melissa Fuson (b) (4)	11 Jan 2021 18:41:57
User entered 'RIB PAIN' reason for change: Data Entry Error	(b) (4) Melissa Fuson (b) (4)	11 Jan 2021 18:41:12
User opened query 'please specify type of pain' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 15:03:33
User entered 'pain'	Jacob sekinger (b) (4)	19 Nov 2020 20:42:09
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:34:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered '8'	(b) (4) Jacob sekinger (b) (4)	19 Nov 2020 20:42:09

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:34:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'mg (mg)'	(b) (4) Jacob sekinger (b) (4) (b) (4)	19 Nov 2020 20:42:09

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:34:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered empty.	(b) (4) Jacob sekinger (b) (4)	19 Nov 2020 20:42:09
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:34:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'once (ONCE)'	(b) (4) Jacob sekinger (b) (4)	19 Nov 2020 20:42:09

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:34:19

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered empty.	(b) (4) Jacob sekinger (b) (4)	19 Nov 2020 20:42:09
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:34:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'Intravenous (INTRAVENOUS)'	Jacob sekinger (b) (4)	19 Nov 2020 20:42:09

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:34:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered empty.	(b) (4) Jacob sekinger (b) (4)	19 Nov 2020 20:42:09
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:34:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered '24 Oct 2020'	(b) (4) Jacob sekinger (b) (4)	19 Nov 2020 20:42:09
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:34:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered '0'	(b) (4) Jacob sekinger (b) (4)	19 Nov 2020 20:42:09

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:34:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'No (N)'	(b) (4) Jacob sekinger (b) (4)	19 Nov 2020 20:42:09
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:34:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered '24 Oct 2020'	(b) (4) Jacob sekinger (b) (4)	19 Nov 2020 20:42:09
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:34:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'No (N)'	(b) (4) Jacob sekinger (b) (4)	19 Nov 2020 20:42:09
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:34:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:12
User entered empty.	System	19 Nov 2020 20:42:09

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:12
User entered empty.	System	19 Nov 2020 20:42:09

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:12
User entered empty.	System	19 Nov 2020 20:42:09

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:34:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:03:46
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 14:07:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 14:07:07
Data point term sent to Coder	System	17 Dec 2020 14:05:58
Coding entries removed.	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 14:05:43
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTI-ACNE PREPARATIONS, ATC: ANTI-ACNE PREPARATIONS FOR TOPICAL USE, ATC: ANTIINFECTIVES FOR TREATMENT OF ACNE, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Dec 2020 17:06:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Dec 2020 17:06:56
Data point term sent to Coder	System	14 Dec 2020 15:42:52
User entered 'AZITHROMYCIN'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:34:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:03:48
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:34:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:03:50
User closed query 'Please correct spelling' (Site from CRA).	(b) (4)	29 Dec 2020 15:03:44
Query 'Please correct spelling' answered with 'CORRECTED SPELLING TO PNEUMONIA' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 14:05:56
User entered 'PNEUMONIA' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 14:05:43
User opened query 'Please correct spelling' (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 21:17:12
User entered 'PNEUMENIA'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:34:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:05:00
User entered '500'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:34:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:04:56
User entered 'mg (mg)'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:34:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:04:54
User entered empty.	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:34:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4), (b) (6)	13 Feb 2021 16:46:40
User closed query 'please confirm - per source daily for 2 days (once/day)?' (Site from CRA).	(b) (4)	13 Feb 2021 16:46:30
Query 'please confirm - per source daily for 2 days (once/day)?' answered with 'UPDATED TO ONCE DAILY FOR TWO DAYS' (Site from CRA).	Melissa Fuson (b) (4)	11 Jan 2021 18:49:04
User entered 'once daily (QD)' reason for change:	Melissa Fuson (b) (4)	11 Jan 2021 18:48:51
Data Entry Error	(b) (4)	
User opened query 'please confirm - per source daily for 2 days (once/day)?' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 15:05:34
User entered 'twice daily (BID)'	Melissa Fuson (b) (4)	14 Dec 2020 15:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:34:19

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:04:50
User entered empty.	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:34:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:04:48
User entered 'Oral (ORAL)'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:34:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:04:43
User entered empty.	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:34:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:04:29
User entered '23 Aug 2020'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:34:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:04:26
User entered '0'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:34:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:04:24
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:34:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:04:23
User entered '24 Aug 2020'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:34:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:04:21
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:34:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:17
User entered '1'	System	11 Jan 2021 18:48:51
User entered '2'	System	14 Dec 2020 15:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:17
User entered '1'	System	14 Dec 2020 15:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:17
User entered '804 (804)'	System	14 Dec 2020 15:41:57

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:34:19

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:06:01
User closed query 'Please correct spelling' (Site from CRA).	(b) (4)	29 Dec 2020 15:05:58
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAZONE, PRODUCTSYNONYM: ROCEPHIN [CEFTRIAZONE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 21:25:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 21:25:49
Data point term sent to Coder	System	17 Dec 2020 14:07:59
Query 'Please correct spelling' answered with 'CORRECTED SPELLING TO ROCEPHIN' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 14:07:11
Coding entries removed.	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 14:06:59
User entered 'ROCEPHIN' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 14:06:59
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAZONE, PRODUCTSYNONYM: ROCEPHIN [CEFTRIAZONE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 00:10:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 00:10:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:34:19

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'Please correct spelling' (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 21:15:58
Data point term sent to Coder	System	14 Dec 2020 15:43:55
User entered 'ROLEPHIN'	Melissa Fuson (b) (4)	14 Dec 2020 15:42:55
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:34:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:06:06
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:42:55

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:34:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:06:09
User entered 'PNEUMONIA'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:42:55

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:34:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:06:22
User entered '2'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:42:55

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:34:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:06:23
User entered 'g (g)'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:42:55

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:34:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:06:25
User entered empty.	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:42:55

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:34:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:06:27
User entered 'once (ONCE)'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:42:55

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:34:19

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:06:35
User entered empty.	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:42:55

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:34:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:06:37
User entered 'Intramuscular (INTRAMUSCULAR)'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:42:55

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:34:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:06:39
User entered empty.	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:42:55

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:34:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:06:41
User entered '23 Aug 2020'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:42:55

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:34:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:06:42
User entered '0'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:42:55

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:34:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:06:45
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:42:55

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:34:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:06:51
User entered '23 Aug 2020'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:42:55

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:34:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:06:54
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:42:55

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:34:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:22
User entered empty.	System	14 Dec 2020 15:42:55

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:22
User entered empty.	System	14 Dec 2020 15:42:55

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:22
User entered empty.	System	14 Dec 2020 15:42:55

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:34:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Dec 2020 01:35:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 01:35:54
Data point term sent to Coder	System	14 Dec 2020 15:47:02
User entered 'LOVENOX'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:46:56

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:34:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'Yes (Y)'	(b) (4) Melissa Fuson (b) (4)	14 Dec 2020 15:46:56

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:34:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'DVT PROPHYLAXIS'	(b) (4) Melissa Fuson (b) (4)	14 Dec 2020 15:46:56

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:34:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered '40'	(b) (4) Melissa Fuson (b) (4)	14 Dec 2020 15:46:56

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:34:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'mg (mg)'	(b) (4) Melissa Fuson (b) (4)	14 Dec 2020 15:46:56

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:34:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered empty.	(b) (4) Melissa Fuson (b) (4)	14 Dec 2020 15:46:56

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:34:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'once daily (QD)'	(b) (4) Melissa Fuson (b) (4)	14 Dec 2020 15:46:56

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:34:19

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered empty.	(b) (4) Melissa Fuson (b) (4)	14 Dec 2020 15:46:56

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:34:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Melissa Fuson (b) (4)	14 Dec 2020 15:46:56

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:34:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered empty.	(b) (4) Melissa Fuson (b) (4)	14 Dec 2020 15:46:56

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:34:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered '23 Aug 2020'	(b) (4) Melissa Fuson (b) (4)	14 Dec 2020 15:46:56

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:34:19

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered '0'	(b) (4) Melissa Fuson (b) (4)	14 Dec 2020 15:46:56

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:34:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4)	14 Dec 2020 15:46:56

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:34:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered '01 Sep 2020'	(b) (4) Melissa Fuson (b) (4)	14 Dec 2020 15:46:56

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:34:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4)	14 Dec 2020 15:46:56

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:34:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:28
User entered '1'	System	14 Dec 2020 15:46:56

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:28
User entered '1'	System	14 Dec 2020 15:46:56

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:28
User entered '804 (804)'	System	14 Dec 2020 15:46:56

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:34:19

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Mar 2021 10:14:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Mar 2021 10:14:49
Data point term sent to Coder Coding entries removed.	System Steven Anderson (b) (4)	15 Mar 2021 20:57:30 15 Mar 2021 20:57:07
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Feb 2021 17:01:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Feb 2021 17:01:50
Data point term sent to Coder Coding entries removed.	System Steven Anderson (b) (4)	10 Feb 2021 17:00:50 10 Feb 2021 17:00:34
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:08:33
User closed query 'Please correct spelling' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 15:07:27

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:34:19

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 16:23:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 16:23:48
Data point term sent to Coder	System	17 Dec 2020 14:07:59
Query 'Please correct spelling' answered with 'CORRECTED SPELLING TO ZOFRAN' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 14:07:55
Coding entries removed.	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 14:07:43
User entered 'ZOFRAN' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 14:07:43
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Dec 2020 22:09:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Dec 2020 22:09:00
User opened query 'Please correct spelling' (Site from CRA).	(b) (4), (b) (6) [REDACTED]	15 Dec 2020 21:16:44
Data point term sent to Coder	System	14 Dec 2020 15:49:03
User entered 'ZOFRAIN'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:48:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:34:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 21:18:38
DataPoint Un-verified.	Steven Anderson (b) (4)	15 Mar 2021 20:57:07
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Steven Anderson (b) (4)	15 Mar 2021 20:57:07
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:08:08
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:48:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:34:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 06:49:44
User closed query 'should this be prophylaxis for nausea?' (Site from CRA).	(b) (4)	15 Mar 2021 21:18:35
Query 'should this be prophylaxis for nausea?' answered with 'this has been updated' (Site from CRA).	Steven Anderson (b) (4)	15 Mar 2021 20:57:22
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' ' answered with 'this has been updated' (Site from DM).	Steven Anderson (b) (4)	15 Mar 2021 20:57:17
User entered 'NAUSEA prophylactic' reason for change: Data Entry Error	Steven Anderson (b) (4)	15 Mar 2021 20:57:07
User opened query 'should this be prophylaxis for nausea?' (Site from CRA).	(b) (4), (b) (6)	13 Mar 2021 18:27:38
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 10:07:54
User closed query 'Per DM CLR: Please review the indication of this medication as PNEUMONIA is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 19:09:13

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:34:19

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review the indication of this medication as PNEUMONIA is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'Per query, this medication is not used for SAE of Pneumonia. site removed pneumonia as indication' (Site from DM). DataPoint Un-verified.	Steven Anderson (b) (4) (b) (4)	10 Feb 2021 17:02:23
User entered 'NAUSEA' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	10 Feb 2021 17:00:34
User opened query 'Per DM CLR: Please review the indication of this medication as PNEUMONIA is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 10:05:55
User entered 'NAUSEA - PNEUMONIA'	Melissa Fuson (b) (4) (b) (4)	29 Dec 2020 15:08:11 14 Dec 2020 15:48:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:34:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:08:15
User entered '4'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:48:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:34:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:08:17
User entered 'mg (mg)'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:48:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:34:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:08:22
User entered empty.	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:48:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:34:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:08:26
User entered 'as needed (PRN)'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:48:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:34:19

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:08:29
User entered empty.	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:48:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:34:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:08:00
User entered 'Intravenous (INTRAVENOUS)'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:48:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:34:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:07:57
User entered empty.	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:48:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:34:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:07:54
User entered '23 Aug 2020'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:48:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:34:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:07:52
User entered '0'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:48:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:34:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:07:50
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:48:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:34:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:07:48
User entered '01 Sep 2020'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:48:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:34:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:07:47
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:48:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:34:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:34
User entered empty.	System	14 Dec 2020 15:48:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:34
User entered empty.	System	14 Dec 2020 15:48:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:22:34
User entered empty.	System	14 Dec 2020 15:48:41

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:34:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:23:33
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:10:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Dec 2020 03:51:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Dec 2020 03:51:47
Data point term sent to Coder	System	14 Dec 2020 15:53:15
Data point term sent to Coder	System	14 Dec 2020 15:50:07
User entered 'MORPHINE'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:49:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:34:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:23:33
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:10:16
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:49:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:34:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:23:33
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User closed query 'Per DM CLR: This Conmed is given for the AE# 02. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and the AE eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:09:24
Query 'Per DM CLR: This Conmed is given for the AE# 02. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and the AE eCRF as appropriate. Otherwise, provide clarification.' answered with 'AE now indicated that CON-med was used. Both con med and CON procedures is checked and both EDC logs will be filled out accordingly' (Site from DM).	Steven Anderson (b) (4) (b) (4)	10 Feb 2021 17:03:13
User opened query 'Per DM CLR: This Conmed is given for the AE# 02. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and the AE eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 10:10:05
DataPoint Verified.		29 Dec 2020 15:10:18
User entered 'RIB PAIN / PNEUMONIA'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:49:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:34:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:23:33
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:10:09
User entered '8'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:49:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:34:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:23:33
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:10:06
User entered 'mg (mg)'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:49:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:34:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:23:33
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:10:04
User entered empty.	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:49:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:34:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:23:33
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:10:03
User entered 'as needed (PRN)'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:49:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:34:19

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:23:33
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:10:01
User entered empty.	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:49:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:34:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:23:33
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:09:56
User entered 'Intravenous (INTRAVENOUS)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:53:10
User entered 'Oral (ORAL)'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:49:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:34:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:23:33
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:09:55
User entered empty.	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:49:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:34:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:23:33
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:09:53
User entered '23 Aug 2020'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:49:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:34:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:23:33
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:09:51
User entered '0'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:49:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:34:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:23:33
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:09:49
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:49:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:34:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:23:33
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:09:06
User entered '01 Sep 2020'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:49:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:34:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:23:33
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:09:03
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:49:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:34:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:23:33
User entered empty.	System	14 Dec 2020 15:49:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:23:33
User entered empty.	System	14 Dec 2020 15:49:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:23:33
User entered empty.	System	14 Dec 2020 15:49:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:34:19

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:23:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 21:20:34
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, PRODUCTSYNONYM: SOLUMEDROL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 21:18:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 21:18:44
Data point term sent to Coder	System	15 Mar 2021 21:02:49
DataPoint Un-verified.	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 21:02:11
Coding entries removed.	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 21:02:11
User entered 'Solumedrol' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 21:02:11
Data point term sent to Coder	System	15 Mar 2021 21:01:47
DataPoint activated with code reason code Data required.	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 21:01:03
Data point term sent to Coder	System	10 Feb 2021 17:04:52
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4) (b) (4)	10 Feb 2021 17:04:49
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:11:20
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN SODIUM;TAZOBACTAM SODIUM, PRODUCTSYNONYM: ZOSYN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Dec 2020 15:53:03

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:34:19

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003. Data point term sent to Coder User entered 'ZOSYN'	Coder Import (b) (4) (b) (4) System Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:53:03 14 Dec 2020 15:52:14 14 Dec 2020 15:51:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:34:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:23:37
User signature succeeded.	Richard Powell (b) (4) (b) (4)	16 Apr 2021 13:30:25
DataPoint activated with code reason code Data required.	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 21:01:03
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4) (b) (4)	10 Feb 2021 17:04:49
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:11:22
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:51:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:34:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:23:37
User signature succeeded.	Richard Powell (b) (4) (b) (4)	16 Apr 2021 13:30:25
DataPoint activated with code reason code Data required.	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 21:01:03
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4) (b) (4)	10 Feb 2021 17:04:49
Query 'Per DM CLR: Please review the dose recorded as this is not the standard for this medication. Please correct the dosage or provide explanation for alternate dosage.' canceled (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 10:12:37
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 10:12:29
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:11:28
User entered 'PNEUMONIA'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:51:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:34:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:23:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 06:50:23
		15 Mar 2021 21:20:29
Query 'Per DM CLR: Please review the dose recorded as this is not the standard for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'this entire med sheet has been updated' (Site from DM). DataPoint Un-verified.	Steven Anderson (b) (4)	15 Mar 2021 21:02:27
		15 Mar 2021 21:02:11
User entered '40' reason for change: Data Entry Error	Steven Anderson (b) (4)	15 Mar 2021 21:02:11
DataPoint activated with code reason code Data required.	Steven Anderson (b) (4)	15 Mar 2021 21:01:03
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4)	10 Feb 2021 17:04:49
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 10:12:48
		29 Dec 2020 15:11:32
User entered '4.5'	Melissa Fuson (b) (4)	14 Dec 2020 15:51:45
		(b) (4)

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:34:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:23:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 21:20:27
DataPoint Un-verified.	Steven Anderson (b) (4)	15 Mar 2021 21:02:11
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4) Steven Anderson (b) (4)	15 Mar 2021 21:02:11
DataPoint activated with code reason code Data required.	(b) (4) Steven Anderson (b) (4)	15 Mar 2021 21:01:03
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4)	10 Feb 2021 17:04:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:11:34
User entered 'g (g)'	Melissa Fuson (b) (4)	14 Dec 2020 15:51:45
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:34:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:23:37
User signature succeeded.	Richard Powell (b) (4) (b) (4)	16 Apr 2021 13:30:25
DataPoint activated with code reason code Data required.	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 21:01:03
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4) (b) (4)	10 Feb 2021 17:04:49
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:11:37
User entered empty.	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:51:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:34:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:23:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 21:20:24
DataPoint Un-verified.	Steven Anderson (b) (4)	15 Mar 2021 21:02:11
User entered 'once daily (QD)' reason for change:	(b) (4)	
Data Entry Error	Steven Anderson (b) (4)	15 Mar 2021 21:02:11
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Steven Anderson (b) (4)	15 Mar 2021 21:01:03
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4)	10 Feb 2021 17:04:49
DataPoint Verified.	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:12:48
User entered 'other (OTHER)'	Melissa Fuson (b) (4)	14 Dec 2020 15:51:45
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:34:19

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:23:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 21:20:26
DataPoint Un-verified.	Steven Anderson (b) (4)	15 Mar 2021 21:02:11
User entered empty; reason for change Data Entry Error	(b) (4) Steven Anderson (b) (4)	15 Mar 2021 21:02:11
DataPoint activated with code reason code Data required.	Steven Anderson (b) (4)	15 Mar 2021 21:01:03
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4)	10 Feb 2021 17:04:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:12:51
User entered 'EVERY 6 HOURS'	Melissa Fuson (b) (4)	14 Dec 2020 15:51:45
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:34:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:23:37
User signature succeeded.	Richard Powell (b) (4) (b) (4)	16 Apr 2021 13:30:25
DataPoint activated with code reason code Data required.	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 21:01:03
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4) (b) (4)	10 Feb 2021 17:04:49
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:12:57
User entered 'Intravenous (INTRAVENOUS)'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:51:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:34:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:23:37
User signature succeeded.	Richard Powell (b) (4) (b) (4)	16 Apr 2021 13:30:25
DataPoint activated with code reason code Data required.	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 21:01:03
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4) (b) (4)	10 Feb 2021 17:04:49
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:13:03
User entered empty.	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:51:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:34:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:23:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 15:30:58
DataPoint Un-verified.	Steven Anderson (b) (4)	15 Mar 2021 21:02:11
User entered '23 Aug 2020' reason for change: Data Entry Error	(b) (4) Steven Anderson (b) (4)	15 Mar 2021 21:02:11
DataPoint activated with code reason code Data required.	(b) (4) Steven Anderson (b) (4)	15 Mar 2021 21:01:03
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4)	10 Feb 2021 17:04:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:13:10
User entered '02 Sep 2020'	Melissa Fuson (b) (4)	14 Dec 2020 15:51:45
	(b) (4)	

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:34:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:23:37
User signature succeeded.	Richard Powell (b) (4) (b) (4)	16 Apr 2021 13:30:25
DataPoint activated with code reason code Data required.	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 21:01:03
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4) (b) (4)	10 Feb 2021 17:04:49
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:13:17
User entered '0'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:51:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:34:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:23:37
User signature succeeded.	Richard Powell (b) (4) (b) (4)	16 Apr 2021 13:30:25
DataPoint activated with code reason code Data required.	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 21:01:03
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4) (b) (4)	10 Feb 2021 17:04:49
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:13:25
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:51:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:34:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:23:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 15:31:00
DataPoint Un-verified.	Steven Anderson (b) (4)	15 Mar 2021 21:02:11
User entered '01 Sep 2020' reason for change: Data Entry Error	(b) (4) Steven Anderson (b) (4)	15 Mar 2021 21:02:11
DataPoint activated with code reason code Data required.	(b) (4) Steven Anderson (b) (4)	15 Mar 2021 21:01:03
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4)	10 Feb 2021 17:04:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:13:27
User entered '22 Sep 2020'	Melissa Fuson (b) (4)	14 Dec 2020 15:51:45
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:34:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:23:37
User signature succeeded.	Richard Powell (b) (4) (b) (4)	16 Apr 2021 13:30:25
DataPoint activated with code reason code Data required.	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 21:01:03
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4) (b) (4)	10 Feb 2021 17:04:49
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:13:31
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:51:45

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:34:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:23:37
User entered '1'	System	15 Mar 2021 21:02:11
DataPoint activated with code reason code Data required.	Steven Anderson (b) (4)	15 Mar 2021 21:01:03
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4)	10 Feb 2021 17:04:49
User entered empty.	System	14 Dec 2020 15:51:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:23:37
User entered '1'	System	15 Mar 2021 21:02:11
DataPoint activated with code reason code Data required.	Steven Anderson (b) (4)	15 Mar 2021 21:01:03
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4)	10 Feb 2021 17:04:49
User entered empty.	System	14 Dec 2020 15:51:45

US3412126

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:34:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:23:37
User entered '804 (804)'	System	15 Mar 2021 21:02:11
DataPoint activated with code reason code Data required.	Steven Anderson (b) (4)	15 Mar 2021 21:01:03
DataPoint inactivated with code reason code Data not required.	(b) (4)	10 Feb 2021 17:04:49
User entered empty.	System	14 Dec 2020 15:51:45

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:34:19

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:31
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:19:20
User closed query 'please add daily ECGs start 23 Aug 2020 - 30 Aug 2020' (Site from CRA).		15 Dec 2020 21:19:15
User closed query 'please add chest xray on 31 Aug 2020 and PICC line insertion on 31 Aug 2020' (Site from CRA).		15 Dec 2020 21:19:13
User closed query 'please add CT pulmonary angiogram on 22 Aug 2020, Chest xray 22 Aug 2020 any cultures done?' (Site from CRA).		15 Dec 2020 21:19:10
Query 'please add daily ECGs start 23 Aug 2020 - 30 Aug 2020' answered with 'ADDED ALL PROCEDURES ' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:58:37
Query 'please add chest xray on 31 Aug 2020 and PICC line insertion on 31 Aug 2020' answered with 'ADDED ALL PROCEDURES ' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:58:33
Query 'please add CT pulmonary angiogram on 22 Aug 2020, Chest xray 22 Aug 2020 any cultures done?' answered with 'ADDED ALL PROCEDURES AND CULTURES WERE NOT DONE.' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:58:26
User opened query 'please add daily ECGs start 23 Aug 2020 - 30 Aug 2020' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 18:37:10
User opened query 'please add chest xray on 31 Aug 2020 and PICC line insertion on 31 Aug 2020' (Site from CRA).		04 Nov 2020 18:30:15
User opened query 'please add CT pulmonary angiogram on 22 Aug 2020, Chest xray 22 Aug 2020 any cultures done?' (Site from CRA).		04 Nov 2020 17:12:26
User closed query 'Please consider adding procedures done during hospitalization, ie, cultures, bronchoscopy, chest Xray, CT pulmonary angiogram' (Site from CRA).		04 Nov 2020 17:12:26
Query 'Please consider adding procedures done during hospitalization, ie, cultures, bronchoscopy, chest Xray, CT pulmonary angiogram' answered with 'updated. ' (Site from CRA).	Jacob sekinger (b) (4) (b) (4)	22 Oct 2020 18:07:46

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:34:19

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	22 Oct 2020 18:06:32
User opened query 'Please consider adding procedures done during hospitalization, ie, cultures, bronchoscopy, chest Xray, CT pulmonary angiogram' (Site from CRA).	(b) (4), (b) (6)	07 Oct 2020 18:14:50
User entered 'No (N)'		07 Aug 2020 14:39:58

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:34:19

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:52:24
User entered '25 Aug 2020'	Jacob sekinger (b) (4) (b) (4)	22 Oct 2020 18:07:36

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:34:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
User closed query 'Pneumonia is not a procedure - should be Bronchoscopy with BAL' (Site from CRA). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:41:53
Query 'Pneumonia is not a procedure - should be Bronchoscopy with BAL' answered with 'UPDATED TO PROPER PROCEDURE/SURGERY' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	29 Dec 2020 15:41:49
User entered 'BRONCHOSCOPY WITH BAL DONE ON 25-AUG-2020)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 14:23:22
User opened query 'Pneumonia is not a procedure - should be Bronchoscopy with BAL' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	17 Dec 2020 14:23:03
User entered 'PNEUMONIA (WITH A BRONCHOSCOPY WITH BAL DONE ON 25-AUG-2020)' reason for change: Data Entry Error DataPoint Verified.	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 21:21:16
User entered 'bronchoscopy with BAL'	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 19:07:25
	(b) (4), (b) (6)	20 Nov 2020 19:07:25
	(b) (4), (b) (6)	04 Nov 2020 16:52:26
	Jacob sekinger (b) (4) (b) (4)	22 Oct 2020 18:07:36

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:34:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
DataPoint Verified.	(b) (4), (b) (6)	13 Feb 2021 16:23:54
User closed query 'Please select Adverse event from drop down and delete pneumonia form next line' (Site from CRA).	(b) (4)	13 Feb 2021 16:23:51
Query 'Please select Adverse event from drop down and delete pneumonia form next line' answered with 'UPDATED TO ADVERSE EVENT AND DELETED PNEUMONIA' (Site from CRA).	Melissa Fuson (b) (4)	11 Jan 2021 19:05:49
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	11 Jan 2021 19:05:24
User opened query 'Please select Adverse event from drop down and delete pneumonia form next line' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 15:47:15
User closed query 'the indication should be pneumonia? Please confirm and update' (Site from CRA).	(b) (4)	29 Dec 2020 15:47:15
Query 'the indication should be pneumonia? Please confirm and update' answered with 'UPDATED INDICATION TO BE PNEUMONIA' (Site from CRA).	Melissa Fuson (b) (4)	17 Dec 2020 14:24:03
User entered 'Other (OTHER)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	17 Dec 2020 14:23:46
User opened query 'the indication should be pneumonia? Please confirm and update' (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 21:20:36
User closed query 'please consider updating to pneumonia since this was done as part of SAE diagnostics' (Site from CRA).	(b) (4)	15 Dec 2020 21:19:54
Query 'please consider updating to pneumonia since this was done as part of SAE diagnostics' answered with 'UPDATED PROCEDURE / SURGERY ' (Site from CRA).	Melissa Fuson (b) (4)	20 Nov 2020 19:07:40
User opened query 'please consider updating to pneumonia since this was done as part of SAE diagnostics' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 16:54:40
User entered 'Medical History (MH)'	Jacob sekinger (b) (4)	22 Oct 2020 18:07:36

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:34:19

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Feb 2021 16:23:56
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4)	11 Jan 2021 19:05:24
DataPoint Un-verified.	(b) (4)	
	Melissa Fuson (b) (4)	17 Dec 2020 14:23:46
User entered 'PNEUMONIA' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	Melissa Fuson (b) (4)	17 Dec 2020 14:23:46
	(b) (4), (b) (6)	
		04 Nov 2020 16:52:29
User entered empty.	Jacob sekinger (b) (4)	22 Oct 2020 18:07:36
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:34:19

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:32:07
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
User closed query 'Per DM CLR: Please review the Date of this procedure as it is out of the expected timeframe with AE#2 Rib Pain (23 AUG 2020 - 22 SEP 2020). Please review and reconcile date of procedure or clarify as necessary. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 19:08:38
DataPoint Verified.		06 Apr 2021 17:13:30
User entered '23 Aug 2020' reason for change: Data Entry Error	Andrea Newlands (b) (4)	06 Apr 2021 12:31:25
Query 'Per DM CLR: Please review the Date of this procedure as it is out of the expected timeframe with AE#2 Rib Pain (23 AUG 2020 - 22 SEP 2020). Please review and reconcile date of procedure or clarify as necessary. ' answered with 'updated' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please review the Date of this procedure as it is out of the expected timeframe with AE#2 Rib Pain (23 AUG 2020 - 22 SEP 2020). Please review and reconcile date of procedure or clarify as necessary. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 10:40:50
User entered '22 Aug 2020'	Melissa Fuson (b) (4)	23 Nov 2020 14:45:45
	(b) (4)	

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:34:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:32:07
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:13:30
User entered 'X-RAY CHEST (PA&LATERAL)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:49:26
User entered 'X-RAY CHEST'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:45:45

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:34:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:32:07
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:13:30
User closed query 'Per DM CLR: Indication = OTHER, however, the noted medical condition in the Other, specify field is recorded in the AE eCRF page. Please reconcile and confirm if indication should recorded as one of the available options (i.e. Adverse Event) as appropriate and ensure Other Action Taken include 'Concomitant Procedure', otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 06:40:00
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	15 Mar 2021 20:58:53
Query 'Per DM CLR: Indication = OTHER, however, the noted medical condition in the Other, specify field is recorded in the AE eCRF page. Please reconcile and confirm if indication should recorded as one of the available options (i.e. Adverse Event) as appropriate and ensure Other Action Taken include 'Concomitant Procedure', otherwise clarify. ' answered with 'this has been updated due to it being because of an AE' (Site from DM).	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 20:58:48
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	15 Mar 2021 20:58:27
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 20:58:27
User opened query 'Per DM CLR: Indication = OTHER, however, the noted medical condition in the Other, specify field is recorded in the AE eCRF page. Please reconcile and confirm if indication should recorded as one of the available options (i.e. Adverse Event) as appropriate and ensure Other Action Taken include 'Concomitant Procedure', otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 16:08:57

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:34:19

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 14:08:41
Query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' answered with 'UPDATED INDICATION TO OTHER FOR RIB PAIN' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 14:27:01
User entered 'Other (OTHER)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 14:26:46
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 14:25:19
User opened query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 08:16:13
User entered 'Adverse Event (AE)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:45:45

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:34:19

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:32:07
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:13:30
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	15 Mar 2021 20:58:53
User entered 'RIB PAIN' reason for change: Data Entry Error	Melissa Fuson (b) (4)	17 Dec 2020 14:26:46
User entered empty.	Melissa Fuson (b) (4)	23 Nov 2020 14:45:45

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:34:19

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:32:12
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:13:18
User entered '22 Aug 2020'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:47:36

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:34:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:32:12
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:13:18
User entered 'CT PULMONARY ANGIOGRAM'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:47:36

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:34:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:32:12
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:13:18
User closed query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' (Site from DM).	(b) (4)	18 Dec 2020 18:12:13
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	17 Dec 2020 14:30:33
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	17 Dec 2020 14:30:15
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	17 Dec 2020 14:30:15
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 14:30:15
Query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' answered with 'UPDATED INDICATION TO DIAGNOSTIC FOR PNEUMONIA AE' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 14:29:54
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	17 Dec 2020 14:29:22
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 14:29:22
User opened query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 08:16:37

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:34:19

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:47:36

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:34:19

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:32:12
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:13:18
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 14:30:33
User entered 'PNEUMONIA' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 14:29:22
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:47:36

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:34:19

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:32:21
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:13:14
User entered '31 Aug 2020'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:51:25

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:34:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:32:21
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:13:14
User entered 'XRAY CHEST (PA&LATERAL)' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	06 Apr 2021 12:29:55
User entered 'SECOND XRAY CHEST (PA&LATERAL)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:51:25

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:34:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:32:21
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:13:14
User entered 'Adverse Event (AE)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:51:25

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:34:19

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:32:21
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:13:14
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:51:25

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:34:19

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:32:24
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:13:02
User entered '31 Aug 2020'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:52:10

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:34:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:32:24
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:13:02
User entered 'PICC LINE INSERTION'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:52:10

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:34:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:32:24
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:13:02
User entered 'Adverse Event (AE)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:52:10

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:34:19

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:32:24
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:13:02
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:52:10

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:34:19

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:32:27
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:12:52
User entered '23 Aug 2020'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:54:25

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:34:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:32:27
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:12:52
User entered 'ECG's DAILY FROM 23-AUG-2020 TO 30-AUG-2020'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:54:25

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:34:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:32:27
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:12:52
User entered 'Adverse Event (AE)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:54:25

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:34:19

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:32:27
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:12:52
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 14:54:25

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:34:19

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:32:46
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:12:45
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Dec 2020 16:16:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Dec 2020 16:16:06
User entered '23 Aug 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 16:16:06
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Dec 2020 15:30:29
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Dec 2020 15:30:29
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:30:29
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Dec 2020 15:28:09
User entered ' Aug 2020' (non-conformant).	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:28:09

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:34:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:32:46
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:12:45
User entered 'INITIAL LABS SHOWED LEUCOCYTOSIS, BLOOD CX SO FARD NGTD'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:28:09

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:34:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:32:46
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:12:45
User entered 'Adverse Event (AE)'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:28:09

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:34:19

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:32:46
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:12:45
User entered empty.	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:28:09

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:34:19

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:32:48
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:12:34
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Dec 2020 16:16:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Dec 2020 16:16:18
User entered '23 Aug 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 16:16:18
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Dec 2020 15:30:14
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Dec 2020 15:30:14
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:30:14
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Dec 2020 15:28:55
User entered ' Aug 2020' (non-conformant).	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:28:55

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:34:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:32:48
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:12:34
User entered 'BAL CULTURES AND CYTOLOGY'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:28:55

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:34:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:32:48
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:12:34
User entered 'Adverse Event (AE)'	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:28:55

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:34:19

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:32:48
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:12:34
User entered empty.	Melissa Fuson (b) (4) (b) (4)	14 Dec 2020 15:28:55

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 17:34:19

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:32:51
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:12:38
User entered '19 Oct 2020'	Andrea Newlands (b) (4) (b) (4)	06 Apr 2021 12:30:57

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 17:34:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:32:51
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:12:38
User entered 'chest CT'	Andrea Newlands (b) (4) (b) (4)	06 Apr 2021 12:30:57

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 17:34:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:32:51
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:12:38
User entered 'Adverse Event (AE)'	Andrea Newlands (b) (4) (b) (4)	06 Apr 2021 12:30:57

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 17:34:19

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:32:51
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:12:38
User entered empty.	Andrea Newlands (b) (4) (b) (4)	06 Apr 2021 12:30:57

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 17:34:19

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:32:55
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:11:53
User entered '20 Jan 2021'	Andrea Newlands (b) (4) (b) (4)	06 Apr 2021 12:31:10

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 17:34:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:32:55
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:11:55
User entered 'chest CT'	Andrea Newlands (b) (4) (b) (4)	06 Apr 2021 12:31:10

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 17:34:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:32:55
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:11:57
User entered 'Adverse Event (AE)'	Andrea Newlands (b) (4) (b) (4)	06 Apr 2021 12:31:10

US3412126

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 17:34:19

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:32:55
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:11:59
User entered empty.	Andrea Newlands (b) (4) (b) (4)	06 Apr 2021 12:31:10

US3412126

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:34:19

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User closed query 'Please correct Month to SEP' (Site from CRA).	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:22:00
Query 'Please correct Month to SEP' answered with 'this has been corrected' (Site from CRA).	Steven Anderson (b) (4)	16 Mar 2021 14:06:32
User entered '21 Sep 2020' reason for change: Data Entry Error	(b) (4)	16 Mar 2021 14:06:25
User opened query 'Please correct Month to SEP' (Site from CRA).	(b) (4), (b) (6)	15 Mar 2021 21:24:17
User closed query 'Please review source an consider updating date to 21 Sep 2020 per ePIP submitted stating she is not candidate for second dose ' (Site from CRA).		15 Mar 2021 21:24:17
Query 'Please review source an consider updating date to 21 Sep 2020 per ePIP submitted stating she is not candidate for second dose ' answered with 'this has been updated per query' (Site from CRA).	Steven Anderson (b) (4)	15 Mar 2021 20:00:46
User entered '21 Nov 2020' reason for change: Data Entry Error	(b) (4)	15 Mar 2021 20:00:27
User opened query 'Please review source an consider updating date to 21 Sep 2020 per ePIP submitted stating she is not candidate for second dose ' (Site from CRA).	(b) (4), (b) (6)	13 Mar 2021 18:39:10
User entered '18 Nov 2020'	Steven Anderson (b) (4)	18 Nov 2020 14:11:53

US3412126

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:34:19

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User closed query 'Per CDM: Primary reason for dosing discontinuation is recorded as AE, however there is no AE recorded as IP withdrawn. Please review and update. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:09:50
Query 'Per CDM: Primary reason for dosing discontinuation is recorded as AE, however there is no AE recorded as IP withdrawn. Please review and update. ' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 16:12:34
User opened query 'Per CDM: Primary reason for dosing discontinuation is recorded as AE, however there is no AE recorded as IP withdrawn. Please review and update. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 19:41:29
User closed query 'Per CDM: Please review if any of the pre defined options suitable to choose instead of choosing the option 'other' (eg: AE or SAE or Protocol deviation etc). Please update as appropriate else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 19:10:44
Query 'Per CDM: Please review if any of the pre defined options suitable to choose instead of choosing the option 'other' (eg: AE or SAE or Protocol deviation etc). Please update as appropriate else clarify. Thank you' answered with 'this can be considered due to the AE due to the subject wanting to withhold the second dose due to the AE. However, it was ultimately the patients decision to not return' (Site from DM).	Steven Anderson (b) (4) (b) (4)	10 Feb 2021 16:48:16
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	10 Feb 2021 16:48:12
User opened query 'Per CDM: Please review if any of the pre defined options suitable to choose instead of choosing the option 'other' (eg: AE or SAE or Protocol deviation etc). Please update as appropriate else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 12:44:00
User closed query 'Per CDM: Please confirm if primary reason for dosing discontinuation can be considered Withdrawal of Consent by the participant.' (Site from DM).		20 Jan 2021 18:06:22

US3412126

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:34:19

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Query 'Per CDM: Please confirm if primary reason for dosing discontinuation can be considered Withdrawal of Consent by the participant.' answered with 'Subject has not agreed ot withdraw consent. due to this site wont mark withdrawn consent ' (Site from DM).	Steven Anderson (b) (4) (b) (4)	15 Jan 2021 19:45:17
User opened query 'Per CDM: Please confirm if primary reason for dosing discontinuation can be considered Withdrawal of Consent by the participant.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 15:48:15
User entered 'Other (OTHER)'	Steven Anderson (b) (4) (b) (4)	18 Nov 2020 14:11:53

US3412126

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User closed query 'Please delete pneumonia - should only say AE #3' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 20:17:29
User closed query 'Per CDM re-query: Response noted; However the update is still not in the required format. Please REMOVE the term "PNEUMONIA" and enter only "AE#3" in this data field. Thank you. ' (Site from DM).	(b) (4)	30 Mar 2021 11:12:44
Query 'Per CDM re-query: Response noted; However the update is still not in the required format. Please REMOVE the term "PNEUMONIA" and enter only "AE#3" in this data field. Thank you. ' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4)	29 Mar 2021 13:53:53
Query 'Please delete pneumonia - should only say AE #3' answered with 'updated' (Site from CRA).	(b) (4)	29 Mar 2021 13:53:34
User entered 'AE#3' reason for change: Data Entry Error	Andrea Newlands (b) (4)	29 Mar 2021 13:53:29
User closed query 'Per CDM re-query: Response noted; However please enter only "AE #3" without extraneous information. Thank you' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 06:25:04
User opened query 'Per CDM re-query: Response noted; However the update is still not in the required format. Please REMOVE the term "PNEUMONIA" and enter only "AE#3" in this data field. Thank you. ' (Site from DM).	(b) (4)	18 Mar 2021 06:25:02
User opened query 'Please delete pneumonia - should only say AE #3' (Site from CRA).	(b) (4)	16 Mar 2021 18:22:43
Query 'Per CDM re-query: Response noted; However please enter only "AE #3" without extraneous information. Thank you' answered with 'this has been corrected' (Site from DM).	Steven Anderson (b) (4)	16 Mar 2021 14:06:38
User entered 'AE#3 PNEUMONIA' reason for change: Data Entry Error	Steven Anderson (b) (4)	16 Mar 2021 14:06:25

US3412126

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
User closed query 'Per CDM: Site response noted, however, please note this is 'Dosing Discontinuation' form, not 'Study Discontinuation' form. Per sponsor review, if reason for dosing discontinuation is AE/SAE, then AE specify field must include '# symbol and 'AE logline number'. Please consider updating AE specify field to include only the '# symbol and 'AE logline number' (i.e. #1 for row 1). (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 05:57:43
User opened query 'Per CDM re-query: Response noted; However please enter only "AE #3" without extraneous information. Thank you' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 05:57:41
User closed query 'please consider updating to note that subject was hospitalized 23 Aug 2020 - 01 Sep 2020 and continued on IV antibiotics following discharge' (Site from CRA).	(b) (4), (b) (6)	15 Mar 2021 21:25:22
User entered 'AE#3 PNEUMONIA IS THE REASON SUBJECT HELD THEIR SECOND DOSE. SUBJECT CONTINUED ON IN THE STUDY AND THEREFOR IS ONLY A DOSING DISCONTINUATION.' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 20:09:55
Query 'please consider updating to note that subject was hospitalized 23 Aug 2020 - 01 Sep 2020 and continued on IV antibiotics following discharge' answered with 'this is in the AE narrative but does not have much to do with why the subject held their dose.' (Site from CRA).	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 20:07:56
Query 'Per CDM: Site response noted, however, please note this is 'Dosing Discontinuation' form, not 'Study Discontinuation' form. Per sponsor review, if reason for dosing discontinuation is AE/SAE, then AE specify field must include '# symbol and 'AE logline number'. Please consider updating AE specify field to include only the '# symbol and 'AE logline number' (i.e. #1 for row 1).' answered with 'narrative has been updated' (Site from DM).	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 20:07:13
User entered 'AE#2 Pneumonia is the reason subject held their second dose. Subject continued on in the study and therefor is only a dosing discontinuation.' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 20:07:02

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
User opened query 'please consider updating to note that subject was hospitalized 23 Aug 2020 - 01 Sep 2020 and continued on IV antibiotics following discharge' (Site from CRA).	(b) (4), (b) (6)	13 Mar 2021 18:34:49
User opened query 'Per CDM: Site response noted, however, please note this is 'Dosing Discontinuation' form, not 'Study Discontinuation' form. Per sponsor review, if reason for dosing discontinuation is AE/SAE, then AE specify field must include '# symbol and 'AE logline number'. Please consider updating AE specify field to include only the '# symbol and 'AE logline number' (i.e. #1 for row 1). (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 15:32:01
Query 'Per CDM: Primary reason for dosing discontinuation is AE. Please enter the associated AE in the format (eg: AE #1) in this data field without any additional details. Please update else clarify in query response. ' canceled (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 15:30:23
User opened query 'Per CDM: Primary reason for dosing discontinuation is AE. Please enter the associated AE in the format (eg: AE #1) in this data field without any additional details. Please update else clarify in query response. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 10:21:40
User entered 'Unclear answers if subject wants to continue in the study, site will maintain contact with subject until clear decision is made. Subject is several months out of window & has not followed protocol.' reason for change: Data Entry Error	Andrea Newlands (b) (4)	19 Feb 2021 15:44:13
User entered 'Patients decision to not come in for second injection and also not following any protocol requirements'	Steven Anderson (b) (4)	18 Nov 2020 14:11:53

US3412126

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:28:21
Query 'Data is required. Please complete.' answered with 'subject is not dropping out of the study ' (Site from System).	Steven Anderson (b) (4) (b) (4)	05 Apr 2021 18:45:40
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 18:45:24
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4) (b) (4)	05 Apr 2021 18:45:24
User entered '5 Apr 2021'	Steven Anderson (b) (4) (b) (4)	05 Apr 2021 18:25:54

US3412126

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:34:19

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:28:24
Query 'Data is required. Please complete.' answered with 'subject is not dropping out of the study ' (Site from System).	Steven Anderson (b) (4) (b) (4)	05 Apr 2021 18:45:44
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 18:45:24
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4) (b) (4)	05 Apr 2021 18:45:24
User entered 'Physician decision (specify) (PHYSICIAN DECISION)'	Steven Anderson (b) (4) (b) (4)	05 Apr 2021 18:25:54

US3412126

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:34:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty; reason for change Data Entry Error	(b) (4)	
	Steven Anderson (b) (4)	05 Apr 2021 18:45:24
User entered 'Due to subject not following protocol defined visits PI has determined this subject withdrawn from study at his discretion.'	(b) (4)	
	Steven Anderson (b) (4)	05 Apr 2021 18:25:54
	(b) (4)	

US3412126

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:34:19

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	Steven Anderson (b) (4)	05 Apr 2021 18:25:54

US3412126

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:34:19

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	Steven Anderson (b) (4)	05 Apr 2021 18:25:54

US3412126

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:34:19

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:31
User signature succeeded.	Richard Powell (b) (4) (b) (4)	16 Apr 2021 14:22:28
User entered empty.	Steven Anderson (b) (4) (b) (4)	05 Apr 2021 18:25:54

US3412126

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:34:19

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
User entered empty.	Steven Anderson (b) (4)	05 Apr 2021 18:25:54

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'USA-US061-2020-MRNA-1273-P301000004'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'Richard'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'Powell'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'OH'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered empty.	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		20 Sep 2020 20:22:17
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:38:35
User entered 'US' (non-conformant).	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '18'	System	22 Apr 2021 13:37:01
User entered '17'	System	19 Apr 2021 18:36:50
User entered '16'	System	07 Apr 2021 14:01:12
User entered '15'	System	16 Mar 2021 15:21:11
User entered '14'	System	19 Feb 2021 17:28:55
User entered '13'	System	18 Feb 2021 22:10:44
User entered '12'	System	18 Dec 2020 15:29:39
User entered '11'	System	14 Dec 2020 20:53:09
User entered '10'	System	25 Nov 2020 14:02:57
User entered '9'	System	23 Nov 2020 21:33:05
User entered '8'	System	12 Nov 2020 01:29:34
User entered '7'	System	28 Oct 2020 13:06:23
User entered '6'	System	27 Oct 2020 13:19:33
User entered '5'	System	22 Oct 2020 16:53:55
User entered '4'	System	02 Oct 2020 12:55:43
User entered '3'	System	22 Sep 2020 13:11:42
User entered '2'	System	20 Sep 2020 20:22:29
User entered '1'	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'USA-US061-2020-MRNA-1273-P301000004'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

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Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Death

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	0 Oct 2020 17:22:19
Reviewed for Safety.		8 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'Richard'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'Powell'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'OH'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered empty.	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		20 Sep 2020 20:22:17
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:38:35
User entered 'US' (non-conformant).	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '18'	System	22 Apr 2021 13:37:01
User entered '17'	System	19 Apr 2021 18:36:50
User entered '16'	System	07 Apr 2021 14:01:12
User entered '15'	System	16 Mar 2021 15:21:11
User entered '14'	System	19 Feb 2021 17:28:55
User entered '13'	System	18 Feb 2021 22:10:44
User entered '12'	System	18 Dec 2020 15:29:39
User entered '11'	System	14 Dec 2020 20:53:09
User entered '10'	System	25 Nov 2020 14:02:57
User entered '9'	System	23 Nov 2020 21:33:05
User entered '8'	System	12 Nov 2020 01:29:34
User entered '7'	System	28 Oct 2020 13:06:23
User entered '6'	System	27 Oct 2020 13:19:33
User entered '5'	System	22 Oct 2020 16:53:55
User entered '4'	System	02 Oct 2020 12:55:43
User entered '3'	System	22 Sep 2020 13:11:42
User entered '2'	System	20 Sep 2020 20:22:29
User entered '1'	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:34:19

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
User entered '28/Aug/2020 13:09'	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:34:19

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.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
User entered '1'	(b) (4), (b) (6)	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'USA-US061-2020-MRNA-1273-P301000004'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'Richard'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'Powell'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'OH'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered empty.	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		20 Sep 2020 20:22:17
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:38:35
User entered 'US' (non-conformant).	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '18'	System	22 Apr 2021 13:37:01
User entered '17'	System	19 Apr 2021 18:36:50
User entered '16'	System	07 Apr 2021 14:01:12
User entered '15'	System	16 Mar 2021 15:21:11
User entered '14'	System	19 Feb 2021 17:28:55
User entered '13'	System	18 Feb 2021 22:10:44
User entered '12'	System	18 Dec 2020 15:29:39
User entered '11'	System	14 Dec 2020 20:53:09
User entered '10'	System	25 Nov 2020 14:02:57
User entered '9'	System	23 Nov 2020 21:33:05
User entered '8'	System	12 Nov 2020 01:29:34
User entered '7'	System	28 Oct 2020 13:06:23
User entered '6'	System	27 Oct 2020 13:19:33
User entered '5'	System	22 Oct 2020 16:53:55
User entered '4'	System	02 Oct 2020 12:55:43
User entered '3'	System	22 Sep 2020 13:11:42
User entered '2'	System	20 Sep 2020 20:22:29
User entered '1'	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:34:19

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
User entered '20/Sep/2020 16:22'	System	20 Sep 2020 20:22:29

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:34:19

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.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:11:30
User entered '1'	(b) (4), (b) (6)	20 Sep 2020 20:22:29

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'USA-US061-2020-MRNA-1273-P301000004'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'Richard'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'Powell'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'OH'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered empty.	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		20 Sep 2020 20:22:17
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:38:35
User entered 'US' (non-conformant).	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '18'	System	22 Apr 2021 13:37:01
User entered '17'	System	19 Apr 2021 18:36:50
User entered '16'	System	07 Apr 2021 14:01:12
User entered '15'	System	16 Mar 2021 15:21:11
User entered '14'	System	19 Feb 2021 17:28:55
User entered '13'	System	18 Feb 2021 22:10:44
User entered '12'	System	18 Dec 2020 15:29:39
User entered '11'	System	14 Dec 2020 20:53:09
User entered '10'	System	25 Nov 2020 14:02:57
User entered '9'	System	23 Nov 2020 21:33:05
User entered '8'	System	12 Nov 2020 01:29:34
User entered '7'	System	28 Oct 2020 13:06:23
User entered '6'	System	27 Oct 2020 13:19:33
User entered '5'	System	22 Oct 2020 16:53:55
User entered '4'	System	02 Oct 2020 12:55:43
User entered '3'	System	22 Sep 2020 13:11:42
User entered '2'	System	20 Sep 2020 20:22:29
User entered '1'	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:34:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
User entered '22/Sep/2020 09:11'	System	22 Sep 2020 13:11:42

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:34:19

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.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		02 Oct 2020 12:55:35
User entered '1'		22 Sep 2020 13:11:42

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'USA-US061-2020-MRNA-1273-P301000004'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'Richard'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'Powell'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'OH'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered empty.	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4)	20 Sep 2020 20:22:17
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:38:35
User entered 'US' (non-conformant).	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '18'	System	22 Apr 2021 13:37:01
User entered '17'	System	19 Apr 2021 18:36:50
User entered '16'	System	07 Apr 2021 14:01:12
User entered '15'	System	16 Mar 2021 15:21:11
User entered '14'	System	19 Feb 2021 17:28:55
User entered '13'	System	18 Feb 2021 22:10:44
User entered '12'	System	18 Dec 2020 15:29:39
User entered '11'	System	14 Dec 2020 20:53:09
User entered '10'	System	25 Nov 2020 14:02:57
User entered '9'	System	23 Nov 2020 21:33:05
User entered '8'	System	12 Nov 2020 01:29:34
User entered '7'	System	28 Oct 2020 13:06:23
User entered '6'	System	27 Oct 2020 13:19:33
User entered '5'	System	22 Oct 2020 16:53:55
User entered '4'	System	02 Oct 2020 12:55:43
User entered '3'	System	22 Sep 2020 13:11:42
User entered '2'	System	20 Sep 2020 20:22:29
User entered '1'	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:34:19

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
User entered '02/Oct/2020 08:55'	System	02 Oct 2020 12:55:43

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:34:19

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.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:53:44
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
User entered '1'	(b) (4), (b) (6)	02 Oct 2020 12:55:43

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'USA-US061-2020-MRNA-1273-P301000004'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Death

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	0 Oct 2020 17:22:19
Reviewed for Safety.		8 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'Richard'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'Powell'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'OH'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered empty.	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:38:35
User entered 'US' (non-conformant).	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '18'	System	22 Apr 2021 13:37:01
User entered '17'	System	19 Apr 2021 18:36:50
User entered '16'	System	07 Apr 2021 14:01:12
User entered '15'	System	16 Mar 2021 15:21:11
User entered '14'	System	19 Feb 2021 17:28:55
User entered '13'	System	18 Feb 2021 22:10:44
User entered '12'	System	18 Dec 2020 15:29:39
User entered '11'	System	14 Dec 2020 20:53:09
User entered '10'	System	25 Nov 2020 14:02:57
User entered '9'	System	23 Nov 2020 21:33:05
User entered '8'	System	12 Nov 2020 01:29:34
User entered '7'	System	28 Oct 2020 13:06:23
User entered '6'	System	27 Oct 2020 13:19:33
User entered '5'	System	22 Oct 2020 16:53:55
User entered '4'	System	02 Oct 2020 12:55:43
User entered '3'	System	22 Sep 2020 13:11:42
User entered '2'	System	20 Sep 2020 20:22:29
User entered '1'	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:34:19

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:55:17
User entered '22/Oct/2020 16:53'	System	22 Oct 2020 16:53:55

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:34:19

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.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	10 Nov 2020 21:55:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 16:54:17
User entered '1'		22 Oct 2020 16:53:55

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'USA-US061-2020-MRNA-1273-P301000004'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'Richard'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'Powell'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'OH'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered empty.	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		20 Sep 2020 20:22:17
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:38:35
User entered 'US' (non-conformant).	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '18'	System	22 Apr 2021 13:37:01
User entered '17'	System	19 Apr 2021 18:36:50
User entered '16'	System	07 Apr 2021 14:01:12
User entered '15'	System	16 Mar 2021 15:21:11
User entered '14'	System	19 Feb 2021 17:28:55
User entered '13'	System	18 Feb 2021 22:10:44
User entered '12'	System	18 Dec 2020 15:29:39
User entered '11'	System	14 Dec 2020 20:53:09
User entered '10'	System	25 Nov 2020 14:02:57
User entered '9'	System	23 Nov 2020 21:33:05
User entered '8'	System	12 Nov 2020 01:29:34
User entered '7'	System	28 Oct 2020 13:06:23
User entered '6'	System	27 Oct 2020 13:19:33
User entered '5'	System	22 Oct 2020 16:53:55
User entered '4'	System	02 Oct 2020 12:55:43
User entered '3'	System	22 Sep 2020 13:11:42
User entered '2'	System	20 Sep 2020 20:22:29
User entered '1'	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:34:19

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:55:17
User entered '27/Oct/2020 13:19'	System	27 Oct 2020 13:19:33

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:34:19

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.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:55:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:06:15
User entered '1'	(b) (4), (b) (6)	27 Oct 2020 13:19:33

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'USA-US061-2020-MRNA-1273-P301000004'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'Richard'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'Powell'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'OH'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered empty.	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		20 Sep 2020 20:22:17
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:38:35
User entered 'US' (non-conformant).	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '18'	System	22 Apr 2021 13:37:01
User entered '17'	System	19 Apr 2021 18:36:50
User entered '16'	System	07 Apr 2021 14:01:12
User entered '15'	System	16 Mar 2021 15:21:11
User entered '14'	System	19 Feb 2021 17:28:55
User entered '13'	System	18 Feb 2021 22:10:44
User entered '12'	System	18 Dec 2020 15:29:39
User entered '11'	System	14 Dec 2020 20:53:09
User entered '10'	System	25 Nov 2020 14:02:57
User entered '9'	System	23 Nov 2020 21:33:05
User entered '8'	System	12 Nov 2020 01:29:34
User entered '7'	System	28 Oct 2020 13:06:23
User entered '6'	System	27 Oct 2020 13:19:33
User entered '5'	System	22 Oct 2020 16:53:55
User entered '4'	System	02 Oct 2020 12:55:43
User entered '3'	System	22 Sep 2020 13:11:42
User entered '2'	System	20 Sep 2020 20:22:29
User entered '1'	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:34:19

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:55:17
User entered '28/Oct/2020 09:06'	System	28 Oct 2020 13:06:23

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:34:19

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.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:28:38
DataPoint Verified.		10 Nov 2020 21:55:17
User entered '1'		28 Oct 2020 13:06:23

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'USA-US061-2020-MRNA-1273-P301000004'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'Richard'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'Powell'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'OH'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered empty.	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		20 Sep 2020 20:22:17
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:38:35
User entered 'US' (non-conformant).	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '18'	System	22 Apr 2021 13:37:01
User entered '17'	System	19 Apr 2021 18:36:50
User entered '16'	System	07 Apr 2021 14:01:12
User entered '15'	System	16 Mar 2021 15:21:11
User entered '14'	System	19 Feb 2021 17:28:55
User entered '13'	System	18 Feb 2021 22:10:44
User entered '12'	System	18 Dec 2020 15:29:39
User entered '11'	System	14 Dec 2020 20:53:09
User entered '10'	System	25 Nov 2020 14:02:57
User entered '9'	System	23 Nov 2020 21:33:05
User entered '8'	System	12 Nov 2020 01:29:34
User entered '7'	System	28 Oct 2020 13:06:23
User entered '6'	System	27 Oct 2020 13:19:33
User entered '5'	System	22 Oct 2020 16:53:55
User entered '4'	System	02 Oct 2020 12:55:43
User entered '3'	System	22 Sep 2020 13:11:42
User entered '2'	System	20 Sep 2020 20:22:29
User entered '1'	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 17:34:19

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:51:54
User entered '12/Nov/2020 01:29'	System	12 Nov 2020 01:29:34

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 17:34:19

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.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	25 Nov 2020 00:51:54
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:32:55
User entered '1'		12 Nov 2020 01:29:34

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'USA-US061-2020-MRNA-1273-P301000004'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'Richard'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'Powell'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'OH'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered empty.	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		20 Sep 2020 20:22:17
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:38:35
User entered 'US' (non-conformant).	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '18'	System	22 Apr 2021 13:37:01
User entered '17'	System	19 Apr 2021 18:36:50
User entered '16'	System	07 Apr 2021 14:01:12
User entered '15'	System	16 Mar 2021 15:21:11
User entered '14'	System	19 Feb 2021 17:28:55
User entered '13'	System	18 Feb 2021 22:10:44
User entered '12'	System	18 Dec 2020 15:29:39
User entered '11'	System	14 Dec 2020 20:53:09
User entered '10'	System	25 Nov 2020 14:02:57
User entered '9'	System	23 Nov 2020 21:33:05
User entered '8'	System	12 Nov 2020 01:29:34
User entered '7'	System	28 Oct 2020 13:06:23
User entered '6'	System	27 Oct 2020 13:19:33
User entered '5'	System	22 Oct 2020 16:53:55
User entered '4'	System	02 Oct 2020 12:55:43
User entered '3'	System	22 Sep 2020 13:11:42
User entered '2'	System	20 Sep 2020 20:22:29
User entered '1'	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 17:34:19

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:51:54
User entered '23/Nov/2020 21:33'	System	23 Nov 2020 21:33:05

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 17:34:19

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.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 14:02:32
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 00:51:54
User entered '1'	(b) (4), (b) (6)	23 Nov 2020 21:33:05

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'USA-US061-2020-MRNA-1273-P301000004'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'Richard'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'Powell'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'OH'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered empty.	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		20 Sep 2020 20:22:17
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:38:35
User entered 'US' (non-conformant).	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '18'	System	22 Apr 2021 13:37:01
User entered '17'	System	19 Apr 2021 18:36:50
User entered '16'	System	07 Apr 2021 14:01:12
User entered '15'	System	16 Mar 2021 15:21:11
User entered '14'	System	19 Feb 2021 17:28:55
User entered '13'	System	18 Feb 2021 22:10:44
User entered '12'	System	18 Dec 2020 15:29:39
User entered '11'	System	14 Dec 2020 20:53:09
User entered '10'	System	25 Nov 2020 14:02:57
User entered '9'	System	23 Nov 2020 21:33:05
User entered '8'	System	12 Nov 2020 01:29:34
User entered '7'	System	28 Oct 2020 13:06:23
User entered '6'	System	27 Oct 2020 13:19:33
User entered '5'	System	22 Oct 2020 16:53:55
User entered '4'	System	02 Oct 2020 12:55:43
User entered '3'	System	22 Sep 2020 13:11:42
User entered '2'	System	20 Sep 2020 20:22:29
User entered '1'	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 17:34:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:11:27
User entered '25/Nov/2020 14:02'	System	25 Nov 2020 14:02:57

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 17:34:19

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.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:11:27
Reviewed for Safety.		14 Dec 2020 20:45:18
User entered '1'		25 Nov 2020 14:02:57

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'USA-US061-2020-MRNA-1273-P301000004'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'Richard'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'Powell'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'OH'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered empty.	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		20 Sep 2020 20:22:17
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:38:35
User entered 'US' (non-conformant).	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '18'	System	22 Apr 2021 13:37:01
User entered '17'	System	19 Apr 2021 18:36:50
User entered '16'	System	07 Apr 2021 14:01:12
User entered '15'	System	16 Mar 2021 15:21:11
User entered '14'	System	19 Feb 2021 17:28:55
User entered '13'	System	18 Feb 2021 22:10:44
User entered '12'	System	18 Dec 2020 15:29:39
User entered '11'	System	14 Dec 2020 20:53:09
User entered '10'	System	25 Nov 2020 14:02:57
User entered '9'	System	23 Nov 2020 21:33:05
User entered '8'	System	12 Nov 2020 01:29:34
User entered '7'	System	28 Oct 2020 13:06:23
User entered '6'	System	27 Oct 2020 13:19:33
User entered '5'	System	22 Oct 2020 16:53:55
User entered '4'	System	02 Oct 2020 12:55:43
User entered '3'	System	22 Sep 2020 13:11:42
User entered '2'	System	20 Sep 2020 20:22:29
User entered '1'	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (11)

Generated On: 09 Jun 2021 17:34:19

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:11:27
User entered '14/Dec/2020 15:53'	System	14 Dec 2020 20:53:09

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (11)

Generated On: 09 Jun 2021 17:34:19

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.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:11:27
Reviewed for Safety.		18 Dec 2020 15:29:22
Un-reviewed for Safety.		14 Dec 2020 20:53:09
User entered '1' reason for change: Data Entry Error		14 Dec 2020 20:53:09
Reviewed for Safety.		14 Dec 2020 20:52:33
User entered '0'		14 Dec 2020 20:51:04

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'USA-US061-2020-MRNA-1273-P301000004'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'Richard'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'Powell'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'OH'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered empty.	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		20 Sep 2020 20:22:17
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:38:35
User entered 'US' (non-conformant).	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '18'	System	22 Apr 2021 13:37:01
User entered '17'	System	19 Apr 2021 18:36:50
User entered '16'	System	07 Apr 2021 14:01:12
User entered '15'	System	16 Mar 2021 15:21:11
User entered '14'	System	19 Feb 2021 17:28:55
User entered '13'	System	18 Feb 2021 22:10:44
User entered '12'	System	18 Dec 2020 15:29:39
User entered '11'	System	14 Dec 2020 20:53:09
User entered '10'	System	25 Nov 2020 14:02:57
User entered '9'	System	23 Nov 2020 21:33:05
User entered '8'	System	12 Nov 2020 01:29:34
User entered '7'	System	28 Oct 2020 13:06:23
User entered '6'	System	27 Oct 2020 13:19:33
User entered '5'	System	22 Oct 2020 16:53:55
User entered '4'	System	02 Oct 2020 12:55:43
User entered '3'	System	22 Sep 2020 13:11:42
User entered '2'	System	20 Sep 2020 20:22:29
User entered '1'	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (12)

Generated On: 09 Jun 2021 17:34:19

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.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4)	18 Dec 2020 15:29:22
User entered '0'	(b) (4)	14 Dec 2020 20:53:09

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'USA-US061-2020-MRNA-1273-P301000004'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'Richard'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'Powell'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'OH'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered empty.	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		20 Sep 2020 20:22:17
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:38:35
User entered 'US' (non-conformant).	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '18'	System	22 Apr 2021 13:37:01
User entered '17'	System	19 Apr 2021 18:36:50
User entered '16'	System	07 Apr 2021 14:01:12
User entered '15'	System	16 Mar 2021 15:21:11
User entered '14'	System	19 Feb 2021 17:28:55
User entered '13'	System	18 Feb 2021 22:10:44
User entered '12'	System	18 Dec 2020 15:29:39
User entered '11'	System	14 Dec 2020 20:53:09
User entered '10'	System	25 Nov 2020 14:02:57
User entered '9'	System	23 Nov 2020 21:33:05
User entered '8'	System	12 Nov 2020 01:29:34
User entered '7'	System	28 Oct 2020 13:06:23
User entered '6'	System	27 Oct 2020 13:19:33
User entered '5'	System	22 Oct 2020 16:53:55
User entered '4'	System	02 Oct 2020 12:55:43
User entered '3'	System	22 Sep 2020 13:11:42
User entered '2'	System	20 Sep 2020 20:22:29
User entered '1'	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (13)

Generated On: 09 Jun 2021 17:34:19

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:11:27
User entered '18/Dec/2020 15:29'	System	18 Dec 2020 15:29:39

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (13)

Generated On: 09 Jun 2021 17:34:19

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.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:11:27
Reviewed for Safety.		18 Feb 2021 22:10:49
User entered '1'		18 Dec 2020 15:29:39

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'USA-US061-2020-MRNA-1273-P301000004'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'Richard'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'Powell'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'OH'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered empty.	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		20 Sep 2020 20:22:17
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:38:35
User entered 'US' (non-conformant).	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '18'	System	22 Apr 2021 13:37:01
User entered '17'	System	19 Apr 2021 18:36:50
User entered '16'	System	07 Apr 2021 14:01:12
User entered '15'	System	16 Mar 2021 15:21:11
User entered '14'	System	19 Feb 2021 17:28:55
User entered '13'	System	18 Feb 2021 22:10:44
User entered '12'	System	18 Dec 2020 15:29:39
User entered '11'	System	14 Dec 2020 20:53:09
User entered '10'	System	25 Nov 2020 14:02:57
User entered '9'	System	23 Nov 2020 21:33:05
User entered '8'	System	12 Nov 2020 01:29:34
User entered '7'	System	28 Oct 2020 13:06:23
User entered '6'	System	27 Oct 2020 13:19:33
User entered '5'	System	22 Oct 2020 16:53:55
User entered '4'	System	02 Oct 2020 12:55:43
User entered '3'	System	22 Sep 2020 13:11:42
User entered '2'	System	20 Sep 2020 20:22:29
User entered '1'	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (14)

Generated On: 09 Jun 2021 17:34:19

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:11:27
User entered '18/Feb/2021 17:10'	System	18 Feb 2021 22:10:44

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (14)

Generated On: 09 Jun 2021 17:34:19

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.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 22:10:49
User entered '1'	(b) (4), (b) (6)	18 Feb 2021 22:10:44

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'USA-US061-2020-MRNA-1273-P301000004'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'Richard'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'Powell'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'OH'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered empty.	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		20 Sep 2020 20:22:17
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:38:35
User entered 'US' (non-conformant).	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '18'	System	22 Apr 2021 13:37:01
User entered '17'	System	19 Apr 2021 18:36:50
User entered '16'	System	07 Apr 2021 14:01:12
User entered '15'	System	16 Mar 2021 15:21:11
User entered '14'	System	19 Feb 2021 17:28:55
User entered '13'	System	18 Feb 2021 22:10:44
User entered '12'	System	18 Dec 2020 15:29:39
User entered '11'	System	14 Dec 2020 20:53:09
User entered '10'	System	25 Nov 2020 14:02:57
User entered '9'	System	23 Nov 2020 21:33:05
User entered '8'	System	12 Nov 2020 01:29:34
User entered '7'	System	28 Oct 2020 13:06:23
User entered '6'	System	27 Oct 2020 13:19:33
User entered '5'	System	22 Oct 2020 16:53:55
User entered '4'	System	02 Oct 2020 12:55:43
User entered '3'	System	22 Sep 2020 13:11:42
User entered '2'	System	20 Sep 2020 20:22:29
User entered '1'	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (15)

Generated On: 09 Jun 2021 17:34:19

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:11:27
User entered '19/Feb/2021 12:28'	System	19 Feb 2021 17:28:55

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (15)

Generated On: 09 Jun 2021 17:34:19

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.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 17:29:18
User entered '1'	(b) (4), (b) (6)	19 Feb 2021 17:28:55

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'USA-US061-2020-MRNA-1273-P301000004'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'Richard'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'Powell'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'OH'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered empty.	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		20 Sep 2020 20:22:17
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:38:35
User entered 'US' (non-conformant).	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '18'	System	22 Apr 2021 13:37:01
User entered '17'	System	19 Apr 2021 18:36:50
User entered '16'	System	07 Apr 2021 14:01:12
User entered '15'	System	16 Mar 2021 15:21:11
User entered '14'	System	19 Feb 2021 17:28:55
User entered '13'	System	18 Feb 2021 22:10:44
User entered '12'	System	18 Dec 2020 15:29:39
User entered '11'	System	14 Dec 2020 20:53:09
User entered '10'	System	25 Nov 2020 14:02:57
User entered '9'	System	23 Nov 2020 21:33:05
User entered '8'	System	12 Nov 2020 01:29:34
User entered '7'	System	28 Oct 2020 13:06:23
User entered '6'	System	27 Oct 2020 13:19:33
User entered '5'	System	22 Oct 2020 16:53:55
User entered '4'	System	02 Oct 2020 12:55:43
User entered '3'	System	22 Sep 2020 13:11:42
User entered '2'	System	20 Sep 2020 20:22:29
User entered '1'	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (16)

Generated On: 09 Jun 2021 17:34:19

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:11:27
User entered '16/Mar/2021 08:21'	System	16 Mar 2021 15:21:11

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (16)

Generated On: 09 Jun 2021 17:34:19

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.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:11:27
Reviewed for Safety.		07 Apr 2021 14:01:00
User entered '1'		16 Mar 2021 15:21:11

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'USA-US061-2020-MRNA-1273-P301000004'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4)	28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'Richard'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'Powell'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'OH'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered empty.	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		20 Sep 2020 20:22:17
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:38:35
User entered 'US' (non-conformant).	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '18'	System	22 Apr 2021 13:37:01
User entered '17'	System	19 Apr 2021 18:36:50
User entered '16'	System	07 Apr 2021 14:01:12
User entered '15'	System	16 Mar 2021 15:21:11
User entered '14'	System	19 Feb 2021 17:28:55
User entered '13'	System	18 Feb 2021 22:10:44
User entered '12'	System	18 Dec 2020 15:29:39
User entered '11'	System	14 Dec 2020 20:53:09
User entered '10'	System	25 Nov 2020 14:02:57
User entered '9'	System	23 Nov 2020 21:33:05
User entered '8'	System	12 Nov 2020 01:29:34
User entered '7'	System	28 Oct 2020 13:06:23
User entered '6'	System	27 Oct 2020 13:19:33
User entered '5'	System	22 Oct 2020 16:53:55
User entered '4'	System	02 Oct 2020 12:55:43
User entered '3'	System	22 Sep 2020 13:11:42
User entered '2'	System	20 Sep 2020 20:22:29
User entered '1'	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (17)

Generated On: 09 Jun 2021 17:34:19

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:11:27
User entered '07/Apr/2021 14:01'	System	07 Apr 2021 14:01:12

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (17)

Generated On: 09 Jun 2021 17:34:19

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 18:36:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:11:27
User entered '1'		07 Apr 2021 14:01:12

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'USA-US061-2020-MRNA-1273-P301000004'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'Richard'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'Powell'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'OH'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered empty.	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		20 Sep 2020 20:22:17
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:38:35
User entered 'US' (non-conformant).	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '18'	System	22 Apr 2021 13:37:01
User entered '17'	System	19 Apr 2021 18:36:50
User entered '16'	System	07 Apr 2021 14:01:12
User entered '15'	System	16 Mar 2021 15:21:11
User entered '14'	System	19 Feb 2021 17:28:55
User entered '13'	System	18 Feb 2021 22:10:44
User entered '12'	System	18 Dec 2020 15:29:39
User entered '11'	System	14 Dec 2020 20:53:09
User entered '10'	System	25 Nov 2020 14:02:57
User entered '9'	System	23 Nov 2020 21:33:05
User entered '8'	System	12 Nov 2020 01:29:34
User entered '7'	System	28 Oct 2020 13:06:23
User entered '6'	System	27 Oct 2020 13:19:33
User entered '5'	System	22 Oct 2020 16:53:55
User entered '4'	System	02 Oct 2020 12:55:43
User entered '3'	System	22 Sep 2020 13:11:42
User entered '2'	System	20 Sep 2020 20:22:29
User entered '1'	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (18)

Generated On: 09 Jun 2021 17:34:19

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:32:15
User entered '19/Apr/2021 14:36'	System	19 Apr 2021 18:36:50

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (18)

Generated On: 09 Jun 2021 17:34:19

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.	Richard Powell (b) (4)	26 Apr 2021 14:40:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:32:15
User entered '1'		19 Apr 2021 18:36:50

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'USA-US061-2020-MRNA-1273-P301000004'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'Yes (Y)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		28 Aug 2020 17:08:53
User entered 'No (N)'	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'Richard'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'Powell'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered 'OH'	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered empty.	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4)	14 Apr 2021 12:11:27
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:01:00
Un-reviewed for Safety.	System	07 Apr 2021 14:00:26
DataPoint Un-verified.	System	07 Apr 2021 14:00:26
User entered empty.	System	07 Apr 2021 14:00:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 20:22:17
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:40
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:40
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 17:08:53
User entered (b) (6)	System	28 Aug 2020 17:08:18

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:22:19
Reviewed for Safety.		20 Sep 2020 20:22:17
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:38:35
User entered 'US' (non-conformant).	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '18'	System	22 Apr 2021 13:37:01
User entered '17'	System	19 Apr 2021 18:36:50
User entered '16'	System	07 Apr 2021 14:01:12
User entered '15'	System	16 Mar 2021 15:21:11
User entered '14'	System	19 Feb 2021 17:28:55
User entered '13'	System	18 Feb 2021 22:10:44
User entered '12'	System	18 Dec 2020 15:29:39
User entered '11'	System	14 Dec 2020 20:53:09
User entered '10'	System	25 Nov 2020 14:02:57
User entered '9'	System	23 Nov 2020 21:33:05
User entered '8'	System	12 Nov 2020 01:29:34
User entered '7'	System	28 Oct 2020 13:06:23
User entered '6'	System	27 Oct 2020 13:19:33
User entered '5'	System	22 Oct 2020 16:53:55
User entered '4'	System	02 Oct 2020 12:55:43
User entered '3'	System	22 Sep 2020 13:11:42
User entered '2'	System	20 Sep 2020 20:22:29
User entered '1'	System	28 Aug 2020 17:09:00

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (19)

Generated On: 09 Jun 2021 17:34:19

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:59
User entered '22/Apr/2021 06:36'	(b) (4) System	22 Apr 2021 13:37:01

US3412126

Folder: SAE USA-US061-2020-MRNA-1273-P301000004

Form: Safety Report Form (19)

Generated On: 09 Jun 2021 17:34:19

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.	Richard Powell (b) (4)	26 Apr 2021 14:40:59
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 13:37:01