

US3232056 (Prod: MediSync Clinical Research Hattiesburg Clinic)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:05:52

All time stamps listed in this document are displayed in GMT

US3232056

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 13:41:41

Generated On: 09 Jun 2021 16:05:52

[Participant ID](#)

US3232056

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

US3232056

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

| | |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 17 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 | SCRN |

US3232056

Folder: Screening

Form: Demographics

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

| | |
|-------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Date of Birth (MMM yyyy) | (b) (6) 1948 |
| Age | 72 |
| Age Units | YEARS |
| Age (Derived) | 72 |
| 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 | True |
| Black | False |
| Asian | False |
| American Indian or Alaska Native | False |
| Native Hawaiian or other Pacific Islander | False |
| Other | False |
| If race is Other, specify _____ | |
| Unknown | False |
| Not reported | False |

US3232056

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

| | |
|-------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Date of Informed Consent (<i>dd MMM yyyy</i>) | 17 AUG 2020 |
| Month and Year of Informed Consent (derived) | AUG 2020 |
| Year of Informed Consent (derived) | 2020 |
| Protocol Version | Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/> |
| Was participant enrolled in the study? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, indicate reason for screen fail | Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/> |
| If reason for screen fail is Other, specify | |
| Was this participant screened previously? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If Yes, previous participant number | |
| Enrollment Trigger | 1 |

US3232056

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3232056

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

Were any significant conditions reported?

Yes ☒

No ☐

US3232056

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

| | |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition | ASTHMA/WHEEZING |
| 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) | |

US3232056

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

| | |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition | COPD |
| 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) | |

US3232056

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

| | |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition | SLEEP APNEA |
| Start date (dd MMM yyyy) | UN UNK 2018 |
| 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 2018 |
| Start Year (derived) | 2018 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

US3232056

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

| | |
|---------------------------------------------------------|------------------------------------------------------------------|
| Condition | TINNITUS |
| Start date (dd MMM yyyy) | 10 AUG 2020 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | AUG 2020 |
| Start Year (derived) | 2020 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

US3232056

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

| | |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition | CATARACTS |
| Start date (dd MMM yyyy) | UN UNK 2018 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2019 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2018 |
| Start Year (derived) | 2018 |
| Stop Month and Year (derived) | JAN 2019 |
| Stop Year (derived) | 2019 |

US3232056

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

| | |
|---------------------------------------------------------|------------------------------------------------------------------|
| Condition | IRRITABLE BOWEL SYNDROME |
| 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) | _____ |

US3232056

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

| | |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition | MIGRAINE HEADACHES |
| Start date (dd MMM yyyy) | UN UNK 1956 |
| 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 1956 |
| Start Year (derived) | 1956 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

US3232056

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

| | |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition | SHINGLES |
| Start date (dd MMM yyyy) | UN UNK 1957 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2000 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1957 |
| Start Year (derived) | 1957 |
| Stop Month and Year (derived) | JAN 2000 |
| Stop Year (derived) | 2000 |

US3232056

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

| | |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition | CARPOL TUNNEL SYNDROME |
| 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) | |

US3232056

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

| | |
|---------------------------------------------------------|------------------------------------------------------------------|
| Condition | DEPRESSION |
| Start date (dd MMM yyyy) | 02 MAR 2020 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | MAR 2020 |
| Start Year (derived) | 2020 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

US3232056

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

| | |
|---------------------------------------------------------|------------------------------------------------------------------|
| Condition | ANXIETY |
| Start date (dd MMM yyyy) | 02 MAR 2020 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | MAR 2020 |
| Start Year (derived) | 2020 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

US3232056

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

| | |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition | BREAST (BILATERAL) CANCER |
| Start date (dd MMM yyyy) | UN UNK 1990 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2015 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1990 |
| Start Year (derived) | 1990 |
| Stop Month and Year (derived) | JAN 2015 |
| Stop Year (derived) | 2015 |

US3232056

Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

| | |
|---------------------------------------------------------|------------------------------------------------------------------|
| Condition | HYSTERECTOMY |
| Start date (dd MMM yyyy) | UN UNK 1997 |
| 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 1997 |
| Start Year (derived) | 1997 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

US3232056

Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

| | |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition | VITAMIN B12 DEFICIENCY |
| Start date (dd MMM yyyy) | UN UNK 2018 |
| 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 2018 |
| Start Year (derived) | 2018 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

US3232056

Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

| | |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition | ANEMIA |
| Start date (dd MMM yyyy) | UN UNK 1994 |
| 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 1994 |
| Start Year (derived) | 1994 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

US3232056

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

| | |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 17 AUG 2020 |
| Time of assessment (00:00-23:59) | 10:00 (24 HR) |
| Vital Signs Date and Time (derived) | 17 AUG 2020 10:00 |
| Height (xxx.x) | 155 cm |
| Weight (xxx.x) | 59.2 kg |
| BMI (xxx.x) | 24.64100 kg/m ² |
| BMI units | KG/M2 |
| Temperature (xxx.x) | 98.5 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 71 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 125 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 65 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3232056

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 AUG 2020

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

US3232056

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

Date of assessment (dd MMM yyyy) 17 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) UN UNK 1997

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) _____

Date of last menstruation unknown False

US3232056

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3232056

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

| | |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 17 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 | VISIT1 |

US3232056

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

What was the date of randomization? (dd MMM yyyy) 17 AUG 2020

What was the participant's randomization number? 186438

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

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

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

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

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

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

Liver Disease Yes ☐
 No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐
 No ☒

US3232056

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

| | |
|--------|---------------|
| Height | ND - Not Done |
| Weight | ND - Not Done |

US3232056

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

| | |
|-------------------------------------|--------------------------------------------------------------------------------------------------------|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| Timepoint | Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 17 AUG 2020 |
| Time of assessment (00:00-23:59) | 10:00 (24 HR) |
| Vital Signs Date and Time (derived) | 17 AUG 2020 10:00 |
| Temperature (xxx.x) | 98.5 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 71 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 125 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 65 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3232056

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

| | |
|-------------------------------------|--------------------------------------------------------------------------------------------------------|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| Timepoint | Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 17 AUG 2020 |
| Time of assessment (00:00-23:59) | 11:45 (24 HR) |
| Vital Signs Date and Time (derived) | 17 AUG 2020 11:45 |
| Temperature (xxx.x) | 96.3 F |
| Route of measurement | Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/> |
| If Other, specify | TEMPORAL |
| Pulse (xxx) | 69 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 116 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 62 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3232056

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 AUG 2020

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

US3232056

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

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) 17 AUG 2020

What was the treatment time? (00:00-23:59) 11:13 (24 HR)

Treatment Date and Time (derived) 17 AUG 2020 11:13

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

What was the frequency of the study treatment dosing? ONCE

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

US3232056

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 17 AUG 2020 |
| Collection time (00:00-23:59) | 10:54 (24 HR) |
| Collection date and time (derived) | 17 AUG 2020 10:54 |

US3232056

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 17 AUG 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 10:55 | 17 AUG 2020 10:55 |
| Nasopharyngeal Swab 2 | No | | |

US3232056

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

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

96.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 11:34

PC Open Date & Time

17 AUG 2020 11:33

PC Close Date & Time

17 AUG 2020 14:03

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.1 °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 | 17 AUG 2020 21:06 |
| PC Open Date & Time | 17 AUG 2020 14:58 |
| PC Close Date & Time | 18 AUG 2020 11:59 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 21:09

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 21:01

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 21:33

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

21 AUG 2020 20:57

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 21:44

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 21:41

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

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

17 AUG 2020 11:35

PC Open Date & Time

17 AUG 2020 11:33

PC Close Date & Time

17 AUG 2020 14:03

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 21:06

PC Open Date & Time

17 AUG 2020 14:58

PC Close Date & Time

18 AUG 2020 11:59

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 21:10

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 21:02

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 21:33

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 20:58

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 21:44

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 21:41

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

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 ☐

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 17 AUG 2020 11:36 |
| PC Open Date & Time | 17 AUG 2020 11:33 |
| PC Close Date & Time | 17 AUG 2020 14:03 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

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 ☐

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 17 AUG 2020 21:08 |
| PC Open Date & Time | 17 AUG 2020 14:58 |
| PC Close Date & Time | 18 AUG 2020 11:59 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

62 of 4306

EAB) (1725)

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:52

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 18 AUG 2020 21:11 |
| PC Open Date & Time | 18 AUG 2020 12:00 |
| PC Close Date & Time | 19 AUG 2020 11:59 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

64 of 4306

EAB) (1725)

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:52

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 19 AUG 2020 21:03 |
| PC Open Date & Time | 19 AUG 2020 12:00 |
| PC Close Date & Time | 20 AUG 2020 11:59 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

66 of 4306

EAB) (1725)

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:52

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 20 AUG 2020 21:34 |
| PC Open Date & Time | 20 AUG 2020 12:00 |
| PC Close Date & Time | 21 AUG 2020 11:59 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

68 of 4306

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:52

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 21 AUG 2020 20:59 |
| PC Open Date & Time | 21 AUG 2020 12:00 |
| PC Close Date & Time | 22 AUG 2020 11:59 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

70 of 4306

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:52

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 22 AUG 2020 21:45 |
| PC Open Date & Time | 22 AUG 2020 12:00 |
| PC Close Date & Time | 23 AUG 2020 11:59 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

72 of 4306

EAB) (1725)

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:52

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 23 AUG 2020 21:42 |
| PC Open Date & Time | 23 AUG 2020 12:00 |
| PC Close Date & Time | 24 AUG 2020 11:59 |

US3232056

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 24 AUG 2020 13:26

PC Open Date & Time 24 AUG 2020 12:00

PC Close Date & Time 25 AUG 2020 11:59

US3232056

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 25 AUG 2020 23:59

PC Open Date & Time 25 AUG 2020 12:00

PC Close Date & Time 26 AUG 2020 11:59

US3232056

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

27 AUG 2020 00:14

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3232056

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

27 AUG 2020 23:16

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3232056

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

28 AUG 2020 20:51

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3232056

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:05:52

| | |
|---------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| 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 | 24 AUG 2020 13:26 |
| PC Open Date & Time | 24 AUG 2020 12:00 |
| PC Close Date & Time | 25 AUG 2020 11:59 |

US3232056

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:05:52

| | |
|---------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| TIMEPOINT | DAY 9 |
| 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 | 25 AUG 2020 23:59 |
| PC Open Date & Time | 25 AUG 2020 12:00 |
| PC Close Date & Time | 26 AUG 2020 11:59 |

US3232056

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:05:52

| | |
|---------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| TIMEPOINT | DAY 10 |
| 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 | 27 AUG 2020 00:15 |
| PC Open Date & Time | 26 AUG 2020 12:00 |
| PC Close Date & Time | 27 AUG 2020 11:59 |

US3232056

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 11

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

No ☒

Yes ☐

PC Time stamp

27 AUG 2020 23:16

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3232056

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 16:05:52

| | |
|---------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| TIMEPOINT | DAY 12 |
| 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 | 28 AUG 2020 20:52 |
| PC Open Date & Time | 28 AUG 2020 12:00 |
| PC Close Date & Time | 29 AUG 2020 11:59 |

US3232056

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3232056

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232056

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3232056

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232056

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3232056

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232056

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

| | |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 14 SEP 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT2 |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

| | |
|-------------------------------------|-------------------------------------------|
| Timepoint | Pre-Dose <input checked="" type="radio"/> |
| | Post-Dose <input type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 14 SEP 2020 |
| Time of assessment (00:00-23:59) | 09:05 (24 HR) |
| Vital Signs Date and Time (derived) | 14 SEP 2020 09:05 |
| Temperature (xxx.x) | 99.1 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 76 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 20 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 114 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 67 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

| | |
|-------------------------------------|--------------------------------------------|
| Timepoint | Pre-Dose <input type="radio"/> |
| | Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 14 SEP 2020 |
| Time of assessment (00:00-23:59) | 10:20 (24 HR) |
| Vital Signs Date and Time (derived) | 14 SEP 2020 10:20 |
| Temperature (xxx.x) | 97.5 F |
| Route of measurement | Oral <input type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input checked="" type="radio"/> |
| If Other, specify | TEMPORAL |
| Pulse (xxx) | 69 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 115 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 64 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 SEP 2020

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

US3232056

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 14 SEP 2020

What was the treatment time? (00:00-23:59) 09:54 (24 HR)

Treatment Date and Time (derived) 14 SEP 2020 09:54

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

US3232056

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 14 SEP 2020 |
| Collection time (00:00-23:59) | 09:08 (24 HR) |
| Collection date and time (derived) | 14 SEP 2020 09:08 |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 14 SEP 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 09:06 | 14 SEP 2020 09:06 |
| Nasopharyngeal Swab 2 | No | | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

14 SEP 2020 10:14

PC Close Date & Time

14 SEP 2020 12:44

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.3 °F

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

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 14 SEP 2020 21:17 |
| PC Open Date & Time | 14 SEP 2020 13:39 |
| PC Close Date & Time | 15 SEP 2020 11:59 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 21:26

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:52

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

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 21:18

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 00:02

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 21:28

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

19 SEP 2020 22:22

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 20:58

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

14 SEP 2020 10:14

PC Close Date & Time

14 SEP 2020 12:44

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 21:18

PC Open Date & Time

14 SEP 2020 13:39

PC Close Date & Time

15 SEP 2020 11:59

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 21:26

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 21:18

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 00:03

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 21:28

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 22:22

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 20:58

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

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 ☐

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

14 SEP 2020 10:14

PC Close Date & Time

14 SEP 2020 12:44

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

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 ☐

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 14 SEP 2020 21:19 |
| PC Open Date & Time | 14 SEP 2020 13:39 |
| PC Close Date & Time | 15 SEP 2020 11:59 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

118 of 4306

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:52

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 15 SEP 2020 21:27 |
| PC Open Date & Time | 15 SEP 2020 12:00 |
| PC Close Date & Time | 16 SEP 2020 11:59 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

120 of 4306

EAB) (1725)

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:52

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 16 SEP 2020 21:19 |
| PC Open Date & Time | 16 SEP 2020 12:00 |
| PC Close Date & Time | 17 SEP 2020 11:59 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:52

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 ☒

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

124 of 4306

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:52

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 18 SEP 2020 21:29 |
| PC Open Date & Time | 18 SEP 2020 12:00 |
| PC Close Date & Time | 19 SEP 2020 11:59 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

126 of 4306

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:52

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 19 SEP 2020 22:23 |
| PC Open Date & Time | 19 SEP 2020 12:00 |
| PC Close Date & Time | 20 SEP 2020 11:59 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:52

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 ☒

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3232056

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232056

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3232056

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232056

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3232056

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 15:42:59

Generated On: 09 Jun 2021 16:05:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232056

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 18 Feb 2021 15:43:00

Generated On: 09 Jun 2021 16:05:52

| | |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 12 OCT 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT3 |

US3232056

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Feb 2021 15:43:00

Generated On: 09 Jun 2021 16:05:52

| | |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 12 OCT 2020 |
| Time of assessment (00:00-23:59) | 09:05 (24 HR) |
| Vital Signs Date and Time (derived) | 12 OCT 2020 09:05 |
| Temperature (xxx.x) | 98.6 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 72 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 115 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 69 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3232056

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Feb 2021 15:43:00

Generated On: 09 Jun 2021 16:05:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 OCT 2020

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

US3232056

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Feb 2021 15:43:00

Generated On: 09 Jun 2021 16:05:52

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 OCT 2020

Collection time (00:00-23:59)

09:08 (24 HR)

Collection date and time (derived)

12 OCT 2020 09:08

US3232056

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 15:43:00

Generated On: 09 Jun 2021 16:05:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 OCT 2020 20:42:13

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3232056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 OCT 2020 22:32:19

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3232056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

| TIMEPOINT | DAY 78 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 03 NOV 2020 04:38:27 |
| Patient Cloud Open Date & Time | 31 OCT 2020 00:01 |
| Patient Cloud Close Date & Time | 04 NOV 2020 23:59 |

US3232056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 NOV 2020 18:00:05

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

| TIMEPOINT | DAY 96 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 NOV 2020 12:00:06

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 DEC 2020 00:02:06

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 DEC 2020 00:02:32

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 DEC 2020 00:31:35

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 DEC 2020 06:50:39

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 DEC 2020 00:02:55

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

| TIMEPOINT | DAY 145 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Have 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 checked="" 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) | False |
| Chills | False |
| Cough | True |
| Shortness of breath | False |
| Difficulty breathing | False |
| Fatigue | False |
| Muscle aches | True |
| Body aches | False |
| Headache | True |
| New loss of taste | False |
| New loss of smell | False |
| Sore throat | False |
| Congestion | False |
| Runny nose | False |
| Nausea | False |
| Vomiting | False |
| Diarrhea | False |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

08 JAN 2021 14:57:54

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 JAN 2021 09:45:38

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

| TIMEPOINT | DAY 159 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Date and time of submission | 20 JAN 2021 06:47:13 |
| Patient Cloud Open Date & Time | 20 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 24 JAN 2021 23:59 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

| | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| TIMEPOINT | DAY 166 |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 27 JAN 2021 00:27:37 |
| Patient Cloud Open Date & Time | 27 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 31 JAN 2021 23:59 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 FEB 2021 00:01:52

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 FEB 2021 08:37:49

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 FEB 2021 00:01:39

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 FEB 2021 06:01:53

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAR 2021 11:46:07

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

| 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 <input type="radio"/> Yes <input checked="" type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Date and time of submission | 10 MAR 2021 00:03:29 |
| Patient Cloud Open Date & Time | 10 MAR 2021 00:01 |
| Patient Cloud Close Date & Time | 14 MAR 2021 23:59 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 MAR 2021 00:14:21

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 MAR 2021 00:21:22

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 MAR 2021 00:03:01

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

| | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| TIMEPOINT | DAY 236 |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 07 APR 2021 03:46:40 |
| Patient Cloud Open Date & Time | 07 APR 2021 00:01 |
| Patient Cloud Close Date & Time | 11 APR 2021 23:59 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 APR 2021 13:11:25

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 APR 2021 02:33:22

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 APR 2021 01:22:06

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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 ☐

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

| TIMEPOINT | DAY 285 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

| | |
|-----------------------------------------------------|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 16 JUN 2021 00:01 |
| Patient Cloud Close Date & Time | 20 JUN 2021 23:59 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

| | |
|-----------------------------------------------------|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 23 JUN 2021 00:01 |
| Patient Cloud Close Date & Time | 27 JUN 2021 23:59 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

| 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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

| | |
|-----------------------------------------------------|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 21 JUL 2021 00:01 |
| Patient Cloud Close Date & Time | 25 JUL 2021 23:59 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

| TIMEPOINT | DAY 348 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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 ☐

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

| TIMEPOINT | DAY 383 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

| | |
|-----------------------------------------------------|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 08 SEP 2021 00:01 |
| Patient Cloud Close Date & Time | 12 SEP 2021 23:59 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

Date and time of submission

| | |
|----------------------------------------------------|-------------------|
| Patient Cloud Open Date & Time | 22 SEP 2021 00:01 |
|----------------------------------------------------|-------------------|

| | |
|-----------------------------------------------------|-------------------|
| Patient Cloud Close Date & Time | 26 SEP 2021 23:59 |
|-----------------------------------------------------|-------------------|

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

| TIMEPOINT | DAY 425 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

| | |
|-----------------------------------------------------|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 13 OCT 2021 00:01 |
| Patient Cloud Close Date & Time | 17 OCT 2021 23:59 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2021 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

| TIMEPOINT | DAY 439 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

| TIMEPOINT | DAY 446 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

Date and time of submission

| | |
|----------------------------------------------------|-------------------|
| Patient Cloud Open Date & Time | 10 NOV 2021 00:01 |
|----------------------------------------------------|-------------------|

| | |
|-----------------------------------------------------|-------------------|
| Patient Cloud Close Date & Time | 14 NOV 2021 23:59 |
|-----------------------------------------------------|-------------------|

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

| TIMEPOINT | DAY 467 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
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| | |
|-----------------------------------------------------|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 01 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 05 DEC 2021 23:59 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
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| | |
|-----------------------------------------------------|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 08 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 12 DEC 2021 23:59 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

[Patient Cloud Close Date & Time](#)

19 DEC 2021 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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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. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
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|-----------------------------------------------------|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 22 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 26 DEC 2021 23:59 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

| TIMEPOINT | DAY 544 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

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16 FEB 2022 00:01

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20 FEB 2022 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 FEB 2022 00:01

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27 FEB 2022 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

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06 MAR 2022 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

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09 MAR 2022 00:01

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13 MAR 2022 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

| TIMEPOINT | DAY 607 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

| TIMEPOINT | DAY 614 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

[Patient Cloud Open Date & Time](#)

20 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 628

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

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

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

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

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

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

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

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

| TIMEPOINT | DAY 635 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

| TIMEPOINT | DAY 649 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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 ☐

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

| TIMEPOINT | DAY 670 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

| | |
|-----------------------------------------------------|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 06 JUL 2022 00:01 |
| Patient Cloud Close Date & Time | 10 JUL 2022 23:59 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

| TIMEPOINT | DAY 698 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

| TIMEPOINT | DAY 705 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

| TIMEPOINT | DAY 719 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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 ☐ Yes ☐

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

Date and time of submission

| | |
|----------------------------------------------------|-------------------|
| Patient Cloud Open Date & Time | 10 AUG 2022 00:01 |
|----------------------------------------------------|-------------------|

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|-----------------------------------------------------|-------------------|
| Patient Cloud Close Date & Time | 14 AUG 2022 23:59 |
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US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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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. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|

Date and time of submission

| | |
|----------------------------------------------------|-------------------|
| Patient Cloud Open Date & Time | 24 AUG 2022 00:01 |
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|-----------------------------------------------------|-------------------|
| Patient Cloud Close Date & Time | 28 AUG 2022 23:59 |
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US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

| 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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

16 OCT 2022 23:59

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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

| | |
|-----------------------------------------------------|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 19 OCT 2022 00:01 |
| Patient Cloud Close Date & Time | 23 OCT 2022 23:59 |

US3232056

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:05:52

| Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other? | Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache? | Date & Time of Submission |
|-------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| No | | 01 MAR 2021 21:44:31 |

US3232056

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:40:17

Generated On: 09 Jun 2021 16:05:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3232056

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:36:48

Generated On: 09 Jun 2021 16:05:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232056

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 13:41:46

Generated On: 09 Jun 2021 16:05:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3232056

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 13:41:46

Generated On: 09 Jun 2021 16:05:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232056

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 13:41:46

Generated On: 09 Jun 2021 16:05:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3232056

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 13:41:46

Generated On: 09 Jun 2021 16:05:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232056

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 13:41:46

Generated On: 09 Jun 2021 16:05:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3232056

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 13:41:46

Generated On: 09 Jun 2021 16:05:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232056

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 13:42:12

Generated On: 09 Jun 2021 16:05:52

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 24 MAR 2021 |
|--------------------------|-------------|

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

| | |
|------------|--------|
| Folder OID | VISIT4 |
|------------|--------|

US3232056

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 13:42:12

Generated On: 09 Jun 2021 16:05:52

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) _____

US3232056

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 13:42:12

Generated On: 09 Jun 2021 16:05:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 MAR 2021

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

US3232056

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 13:42:12

Generated On: 09 Jun 2021 16:05:52

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 24 MAR 2021 |
| Collection time (00:00-23:59) | 09:40 (24 HR) |
| Collection date and time (derived) | 24 MAR 2021 09:40 |

US3232056

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 13:42:12

Generated On: 09 Jun 2021 16:05:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232056

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 16:00:21

Generated On: 09 Jun 2021 16:05:52

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3232056

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 16:00:21

Generated On: 09 Jun 2021 16:05:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232056

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:52

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 02 Apr 2021 13:41:43

Generated On: 09 Jun 2021 16:05:52

| | |
|--------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Date of Contact | 08 JAN 2021 |
| Time of Contact | 11:59 |
| Date and Time of Contact (derived) | 08 JAN 2021 11:59 |
| Type of Contact | <div>Clinic Visit - Scheduled <input checked="" type="radio"/></div> <div>Clinical Visit - Unscheduled <input type="radio"/></div> <div>Safety Call <input type="radio"/></div> <div>Convalescent Tele-visit <input type="radio"/></div> |
| Has the subject reported symptoms of SARS-COV-2? | <div>Yes <input checked="" type="radio"/></div> <div>No <input type="radio"/></div> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------|---------------|----------------------------------|
| | 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 | 02 JAN 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | ND - Not Done | |
| O2 Saturation Units | % | |
| Temperature | ND - Not Done | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

PRODUCTION RELEASE (v12.003
EAB) (1725)

345 of 4306

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|------------------------|----------|----------------------------------|
| | 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 type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input type="radio"/> |
| | Mild | <input checked="" 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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------|---------------|----------------------------------|
| | 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 | 03 JAN 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | ND - Not Done | |
| O2 Saturation Units | % | |
| Temperature | ND - Not Done | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

PRODUCTION RELEASE (v12.003
EAB) (1725)

349 of 4306

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|------------------------|----------|----------------------------------|
| | 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 type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input type="radio"/> |
| | Mild | <input checked="" 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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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 ☐

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------|---------------|----------------------------------|
| | 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 | 04 JAN 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | ND - Not Done | |
| O2 Saturation Units | % | |
| Temperature | ND - Not Done | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

353 of 4306

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|------------------------|----------|----------------------------------|
| | 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 type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input type="radio"/> |
| | Mild | <input checked="" 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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------|---------------|----------------------------------|
| | 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 JAN 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | ND - Not Done | |
| O2 Saturation Units | % | |
| Temperature | ND - Not Done | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

357 of 4306

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|------------------------|----------|----------------------------------|
| | 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 type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input type="radio"/> |
| | Mild | <input checked="" 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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------|---------------|----------------------------------|
| | 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 JAN 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | ND - Not Done | |
| O2 Saturation Units | % | |
| Temperature | ND - Not Done | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

361 of 4306

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|------------------------|----------|----------------------------------|
| | 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 type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input type="radio"/> |
| | Mild | <input checked="" 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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------|---------------|----------------------------------|
| | 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 JAN 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | ND - Not Done | |
| O2 Saturation Units | % | |
| Temperature | ND - Not Done | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

PRODUCTION RELEASE (v12.003
EAB) (1725)

365 of 4306

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|------------------------|----------|----------------------------------|
| | 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 type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input type="radio"/> |
| | Mild | <input checked="" 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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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 ☐

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|--|--------|--------------------------|
| | 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 JAN 2021 |
|------|-------------|

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

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

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

| | |
|-------------|--------|
| Temperature | 98.8 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"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

369 of 4306

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|------------------------|----------|----------------------------------|
| | 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 type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input type="radio"/> |
| | Mild | <input checked="" 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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------|-------------|----------------------------------|
| | 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 JAN 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | 97 % | |
| O2 Saturation Units | % | |
| Temperature | 98.4 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"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

373 of 4306

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|------------------------|----------|----------------------------------|
| | 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 type="radio"/> |
| | Mild | <input checked="" 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 checked="" 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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------|-------------|----------------------------------|
| | 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 JAN 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | 96 % | |
| O2 Saturation Units | % | |
| Temperature | 97.9 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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|------------------------|----------|----------------------------------|
| | 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 type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input type="radio"/> |
| | Mild | <input checked="" 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"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

378 of 4306

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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 ☐

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------|-------------|----------------------------------|
| | 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 JAN 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | 98 % | |
| O2 Saturation Units | % | |
| Temperature | 97.6 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"/> |

PRODUCTION RELEASE (v12.003
EAB) (1725)

381 of 4306

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|------------------------|----------|----------------------------------|
| | 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 type="radio"/> |
| | Mild | <input checked="" 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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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 ☐

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------|-------------|----------------------------------|
| | 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 JAN 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | 97 % | |
| O2 Saturation Units | % | |
| Temperature | 97.6 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"/> |

PRODUCTION RELEASE (v12.003
EAB) (1725)

385 of 4306

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|------------------------|----------|----------------------------------|
| | 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 type="radio"/> |
| | Mild | <input checked="" 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"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

386 of 4306

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------|-------------|----------------------------------|
| | 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 JAN 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | 97 % | |
| O2 Saturation Units | % | |
| Temperature | 97.6 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"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

389 of 4306

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|------------------------|----------|----------------------------------|
| | 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 type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" 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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------|-------------|----------------------------------|
| | 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 JAN 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | 97 % | |
| O2 Saturation Units | % | |
| Temperature | 97.4 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"/> |

PRODUCTION RELEASE (v12.003
EAB) (1725)

393 of 4306

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|------------------------|----------|----------------------------------|
| | 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 type="radio"/> |
| | Mild | <input checked="" 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"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

394 of 4306

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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 ☐

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------|-------------|----------------------------------|
| | 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 JAN 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | 97 % | |
| O2 Saturation Units | % | |
| Temperature | 97.7 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"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

397 of 4306

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|------------------------|----------|----------------------------------|
| | 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"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

398 of 4306

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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 type="checkbox"/> |
| Day 15 | <input checked="" 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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|--|--------|--------------------------|
| | 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 JAN 2021 |
|------|-------------|

| | |
|---------------------|------|
| 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"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

401 of 4306

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|------------------------|----------|--------------------------|
| | 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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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 type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input checked="" 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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|--|--------|--------------------------|
| | 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 JAN 2021 |
|------|-------------|

| | |
|---------------------|------|
| 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"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

405 of 4306

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|------------------------|----------|--------------------------|
| | 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"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

406 of 4306

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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 type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input checked="" 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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|--|--------|--------------------------|
| | 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 JAN 2021 |
|------|-------------|

| | |
|---------------------|------|
| 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"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

409 of 4306

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|------------------------|----------|--------------------------|
| | 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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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 type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input checked="" 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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------|----------------------|--------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 19 JAN 2021 | |
| Assessment Not Done | True | |
| O2 Saturation | <input type="text"/> | |
| O2 Saturation Units | <input type="text"/> | |
| Temperature | <input type="text"/> | |
| 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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|------------------------|----------|--------------------------|
| | 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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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 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 checked="" 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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 20 JAN 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | 97 % | |
| O2 Saturation Units | % | |
| Temperature | 97.6 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"/> |

PRODUCTION RELEASE (v12.003
EAB) (1725)

417 of 4306

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|------------------------|----------|----------------------------------|
| | 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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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 ☐

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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 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 checked="" 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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 21 JAN 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | 94 % | |
| O2 Saturation Units | % | |
| Temperature | 98.4 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"/> |

PRODUCTION RELEASE (v12.003
EAB) (1725)

421 of 4306

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|------------------------|----------|----------------------------------|
| | 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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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 ☐

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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 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 checked="" 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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------|-------------|----------------------------------|
| | 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 | 22 JAN 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | 97 % | |
| O2 Saturation Units | % | |
| Temperature | 98.5 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 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"/> |

PRODUCTION RELEASE (v12.003
EAB) (1725)

425 of 4306

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|------------------------|----------|----------------------------------|
| | 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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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 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 checked="" 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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------|-------------|----------------------------------|
| | 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 | 23 JAN 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | 96 % | |
| O2 Saturation Units | % | |
| Temperature | 99.5 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 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"/> |

PRODUCTION RELEASE (v12.003
EAB) (1725)

429 of 4306

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|------------------------|----------|----------------------------------|
| | 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"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

430 of 4306

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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 ☐

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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 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 checked="" 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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------|-------------|----------------------------------|
| | 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 | 24 JAN 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | 97 % | |
| O2 Saturation Units | % | |
| Temperature | 97.7 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"/> |

PRODUCTION RELEASE (v12.003
EAB) (1725)

433 of 4306

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|------------------------|----------|----------------------------------|
| | 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"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

434 of 4306

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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 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 checked="" 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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|--|--------|--------------------------|
| | 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 | 25 JAN 2021 |
|------|-------------|

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

| | |
|---------------|------|
| O2 Saturation | 94 % |
|---------------|------|

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

| | |
|-------------|--------|
| Temperature | 98.7 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"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

437 of 4306

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|------------------------|----------|----------------------------------|
| | 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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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 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 checked="" 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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------|-------------|----------------------------------|
| | 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 | 26 JAN 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | 97 % | |
| O2 Saturation Units | % | |
| Temperature | 98.6 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"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

441 of 4306

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|------------------------|----------|----------------------------------|
| | 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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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 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 checked="" 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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------|-------------|----------------------------------|
| | 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 | 27 JAN 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | 91 % | |
| O2 Saturation Units | % | |
| Temperature | 98.7 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"/> |

PRODUCTION RELEASE (v12.003
EAB) (1725)

445 of 4306

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|------------------------|----------|----------------------------------|
| | 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 type="radio"/> |
| | Mild | <input checked="" 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"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

446 of 4306

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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 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 checked="" 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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------|-------------|----------------------------------|
| | 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 | 28 JAN 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | 97 % | |
| O2 Saturation Units | % | |
| Temperature | 97.7 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"/> |

PRODUCTION RELEASE (v12.003
EAB) (1725)

449 of 4306

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

| | | |
|------------------------|----------|----------------------------------|
| | 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"/> |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Data signed: (b) (4) 02 Apr 2021 13:41:44

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 02 Apr 2021 13:41:43

Generated On: 09 Jun 2021 16:05:52

| | |
|-------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Date of Visit | 08 JAN 2021 |
| Was the Subject Tested For SARS-CoV-2 by RT-PCR? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Did Subject Test Positive For SARS-CoV-2 by RT-PCR? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of Test | 08 JAN 2021 |
| Type of Test Performed | Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/> |
| Other, specify | |
| Was this diagnostic test performed at a lab other than the Study Central Lab? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If yes, provide lab information below | |
| Lab/ Institution Test Performed | |
| CLIA Certified? | Yes <input type="radio"/> No <input type="radio"/> |
| COVID-19 Positive (CSA Programming Field Only) | 1 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 02 Apr 2021 13:41:43

Generated On: 09 Jun 2021 16:05:52

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ $\leq 93\%$ on room air at sea level? Yes ☒ No ☐

If Yes, provide:

Start Date 27 JAN 2021

End Date 28 JAN 2021

Oxygen Saturation 91 %

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date _____

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 02 Apr 2021 13:41:43

Generated On: 09 Jun 2021 16:05:52

If Yes to either Did subject require any of the following:

Ventilator Support:

High-Flow Oxygen? Yes ☐
No ☐

Start Date

End Date

Non-Invasive Ventilation? Yes ☐
No ☐

Start Date

End Date

Mechanical Ventilation? Yes ☐
No ☐

Start Date

End Date

ECMO? Yes ☐
No ☐

Start Date

End Date

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐
No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐
No ☐

Start Date

End Date

Acute Renal Dysfunction? Yes ☐
No ☐

Start Date

PRODUCTION RELEASE (v12.003

EAB) (1725)

454 of 4306

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 02 Apr 2021 13:41:43

Generated On: 09 Jun 2021 16:05:52

Hepatic Dysfunction? Yes ☐
No ☐

Start Date

Neurologic Dysfunction? Yes ☐
No ☐

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☒

Date of Assessment

Radiographical Evidence Yes ☐
No ☒

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐
No ☒

Start Date

End Date

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 02 Apr 2021 13:41:43

Generated On: 09 Jun 2021 16:05:52

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: COVID-19 Contact

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

| | |
|--------------------------------------------------|-----------------------------------------------------------|
| Date of Contact | 16 APR 2021 |
| Time of Contact | 14:33 |
| Date and Time of Contact (derived) | 16 APR 2021 14:33 |
| Type of Contact | Clinic Visit - Scheduled <input checked="" type="radio"/> |
| | Clinical Visit - Unscheduled <input type="radio"/> |
| | Safety Call <input type="radio"/> |
| | Convalescent Tele-visit <input type="radio"/> |
| Has the subject reported symptoms of SARS-COV-2? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

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"/> |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------|-------------|----------------------------------|
| | 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 APR 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | 96 % | |
| O2 Saturation Units | % | |
| Temperature | 98.3 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"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

459 of 4306

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

| | | |
|------------------------|----------|----------------------------------|
| | 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 type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" 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"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

460 of 4306

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

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 ☐

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

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"/> |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

| | | |
|--|--------|--------------------------|
| | 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 APR 2021 |
|------|-------------|

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

| | |
|---------------|------|
| O2 Saturation | 94 % |
|---------------|------|

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

| | |
|-------------|--------|
| Temperature | 97.7 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"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

463 of 4306

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

| | | |
|------------------------|----------|----------------------------------|
| | 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"/> |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

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 ☐

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

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"/> |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------|-------------|----------------------------------|
| | 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 APR 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | 91 % | |
| 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"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

467 of 4306

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

| | | |
|------------------------|----------|----------------------------------|
| | 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"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

468 of 4306

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

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 ☐

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

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"/> |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

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

| | |
|------|-------------|
| Date | 19 APR 2021 |
|------|-------------|

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

| | |
|---------------|------|
| O2 Saturation | 95 % |
|---------------|------|

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

| | |
|-------------|--------|
| Temperature | 98.4 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"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

471 of 4306

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

| | | |
|------------------------|----------|----------------------------------|
| | 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"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

472 of 4306

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

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 ☐

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

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"/> |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

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

| | |
|------|-------------|
| Date | 20 APR 2021 |
|------|-------------|

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

| | |
|---------------|------|
| O2 Saturation | 95 % |
|---------------|------|

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

| | |
|-------------|--------|
| Temperature | 98.4 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"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

475 of 4306

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

| | | |
|------------------------|----------|----------------------------------|
| | 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"/> |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

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 ☐

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:05:52

Date of Visit

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

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)

US3232056

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 02 Apr 2021 13:41:45

Generated On: 09 Jun 2021 16:05:52

| Visit | Was Saliva Collected? | Date of Collection |
|--------|-----------------------|--------------------|
| Day 3 | Yes | 10 JAN 2021 |
| Day 5 | Yes | 12 JAN 2021 |
| Day 7 | Yes | 14 JAN 2021 |
| Day 9 | Yes | 16 JAN 2021 |
| Day 14 | Yes | 21 JAN 2021 |
| Day 21 | Yes | 28 JAN 2021 |
| Day 28 | Yes | 05 FEB 2021 |

US3232056

Folder: Illness Visit (2)

Form: Saliva Collection

Generated On: 09 Jun 2021 16:05:52

| Visit | Was Saliva Collected? | Date of Collection |
|--------|-----------------------|--------------------|
| Day 3 | | |
| Day 5 | | |
| Day 7 | | |
| Day 9 | | |
| Day 14 | | |
| Day 21 | | |
| Day 28 | | |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 13:41:45

Generated On: 09 Jun 2021 16:05:52

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 08 JAN 2021 |
|--------------------------|-------------|

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

| | |
|------------|--------|
| Folder OID | SICKD1 |
|------------|--------|

US3232056

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Apr 2021 15:21:05

Generated On: 09 Jun 2021 16:05:52

| | |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 08 JAN 2021 |
| Time of assessment (00:00-23:59) | 12:10 (24 HR) |
| Vital Signs Date and Time (derived) | 08 JAN 2021 12:10 |
| Height (xxx.x) | 155 cm |
| Weight (xxx.x) | 59.9 kg |
| Temperature (xxx.x) | 98.8 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 69 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 22 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 179 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 72 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 13:41:45

Generated On: 09 Jun 2021 16:05:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 JAN 2021

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

US3232056

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 02 Apr 2021 13:41:45

Generated On: 09 Jun 2021 16:05:52

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

08 JAN 2021

US3232056

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 23 Apr 2021 15:21:05

Generated On: 09 Jun 2021 16:05:52

| | |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 16 APR 2021 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | SICKD1 |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Apr 2021 15:21:05

Generated On: 09 Jun 2021 16:05:52

| | |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 16 APR 2021 |
| Time of assessment (00:00-23:59) | 14:33 (24 HR) |
| Vital Signs Date and Time (derived) | 16 APR 2021 14:33 |
| Height (xxx.x) | 156 cm |
| Weight (xxx.x) | 54 kg |
| Temperature (xxx.x) | 98.3 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 71 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 12 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 116 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 57 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Apr 2021 15:21:05

Generated On: 09 Jun 2021 16:05:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 APR 2021

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

US3232056

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 23 Apr 2021 15:21:05

Generated On: 09 Jun 2021 16:05:52

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

16 APR 2021

US3232056

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 13:41:43

Generated On: 09 Jun 2021 16:05:52

| | |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 05 FEB 2021 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | SICKD28 |

US3232056

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 13:41:43

Generated On: 09 Jun 2021 16:05:52

| | |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 05 FEB 2021 |
| Time of assessment (00:00-23:59) | 08:57 (24 HR) |
| Vital Signs Date and Time (derived) | 05 FEB 2021 08:57 |
| Height (xxx.x) | 155 cm |
| Weight (xxx.x) | 52.6 kg |
| Temperature (xxx.x) | 98.5 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 71 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 107 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 58 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3232056

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 13:41:43

Generated On: 09 Jun 2021 16:05:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 FEB 2021

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

US3232056

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 02 Apr 2021 13:41:43

Generated On: 09 Jun 2021 16:05:52

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

05 FEB 2021

US3232056

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:52

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 _____

US3232056

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

| | |
|-------------------------------------------|-----------------------------------|
| Were vital signs assessed? | Yes <input type="checkbox"/> |
| | No <input type="checkbox"/> |
| 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="checkbox"/> |
| | Axillary <input type="checkbox"/> |
| | Other <input type="checkbox"/> |
| 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 | |
| Height (derived) | |
| Weight (derived) | |

US3232056

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:52

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.

US3232056

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 16:05:52

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

US3232056

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 13:41:46

Generated On: 09 Jun 2021 16:05:52

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 11 FEB 2021 |
|--------------------------|-------------|

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

| | |
|------------|---------------|
| Folder OID | UNBLND_DECIDE |
|------------|---------------|

US3232056

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

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 13:41:46

Generated On: 09 Jun 2021 16:05:52

| | |
|-----------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|
| Date of updated informed consent (<i>dd MMM yyyy</i>) | 11 FEB 2021 |
| N/A - Subject Unblinded under Amendment 5 and Discontinued from Study | False |
| Was the participant unblinded? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Under what version of the Protocol was the Participant unblinded? | Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/> |
| Date of unblinding (<i>dd MMM yyyy</i>) | 11 FEB 2021 |
| Participant randomization assignment | mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> |
| Actual Dose 1 | mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/> |
| Actual Dose 2 | mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/> |
| Will participant receive mRNA-1273? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Placebo Only Flag | 1 |
| Continuing with mRNA-1273 | 1 |

US3232056

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 02 Apr 2021 13:41:46

Generated On: 09 Jun 2021 16:05:52

| | |
|-------------|----------|
| Height | 156.5 cm |
| Weight | 57.5 kg |
| BMI (xxx.x) | 23.47681 |

US3232056

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 13:41:46

Generated On: 09 Jun 2021 16:05:52

| | |
|-------------------------------------|--------------------------------------------------------------------------------------------------------|
| Height | 156.5 cm |
| Weight | 57.5 kg |
| BMI (xxx.x) | 23.47681 |
| Timepoint | Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 11 FEB 2021 |
| Time of assessment (00:00-23:59) | 09:11 (24 HR) |
| Vital Signs Date and Time (derived) | 11 FEB 2021 09:11 |
| Temperature (xxx.x) | 98.0 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 68 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 20 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 133 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 72 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3232056

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 13:41:46

Generated On: 09 Jun 2021 16:05:52

| | |
|-------------------------------------|--------------------------------------------------------------------------------------------------------|
| Height | 156.5 cm |
| Weight | 57.5 kg |
| BMI (xxx.x) | 23.47681 |
| Timepoint | Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 11 FEB 2021 |
| Time of assessment (00:00-23:59) | 09:50 (24 HR) |
| Vital Signs Date and Time (derived) | 11 FEB 2021 09:50 |
| Temperature (xxx.x) | 97.2 F |
| Route of measurement | Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/> |
| If Other, specify | TEMPORAL |
| Pulse (xxx) | 69 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 20 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 128 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 70 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3232056

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

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 13:41:46

Generated On: 09 Jun 2021 16:05:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 FEB 2021

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

US3232056

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

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 13:41:46

Generated On: 09 Jun 2021 16:05:52

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 11 FEB 2021

What was the treatment time? (00:00-23:59) 09:42 (24 HR)

Treatment Date and Time (derived) 11 FEB 2021 09:42

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

US3232056

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 13:41:46

Generated On: 09 Jun 2021 16:05:52

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 FEB 2021

Collection time (00:00-23:59)

09:15 (24 HR)

Collection date and time (derived)

11 FEB 2021 09:15

US3232056

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 13:41:46

Generated On: 09 Jun 2021 16:05:52

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 11 FEB 2021 |
| Collection time (00:00 - 23:59) | 09:12 |
| Collection Date and Time (derived) | 11 FEB 2021 09:12 |

US3232056

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

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 13:41:46

Generated On: 09 Jun 2021 16:05:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232056

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 13:42:12

Generated On: 09 Jun 2021 16:05:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3232056

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 13:42:12

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 13:41:45

Generated On: 09 Jun 2021 16:05:52

| | |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 11 MAR 2021 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | OLD29 |

US3232056

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 13:41:45

Generated On: 09 Jun 2021 16:05:52

| | |
|-------------------------------------|-------------------------------------------|
| Timepoint | Pre-Dose <input checked="" type="radio"/> |
| | Post-Dose <input type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 11 MAR 2021 |
| Time of assessment (00:00-23:59) | 08:13 (24 HR) |
| Vital Signs Date and Time (derived) | 11 MAR 2021 08:13 |
| Temperature (xxx.x) | 98.1 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 65 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 122 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 59 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3232056

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 13:41:45

Generated On: 09 Jun 2021 16:05:52

| | |
|-------------------------------------|--------------------------------------------|
| Timepoint | Pre-Dose <input type="radio"/> |
| | Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 11 MAR 2021 |
| Time of assessment (00:00-23:59) | 09:18 (24 HR) |
| Vital Signs Date and Time (derived) | 11 MAR 2021 09:18 |
| Temperature (xxx.x) | 98.6 F |
| Route of measurement | Oral <input type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input checked="" type="radio"/> |
| If Other, specify | TEMPORAL |
| Pulse (xxx) | 62 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 130 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 60 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3232056

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 13:41:45

Generated On: 09 Jun 2021 16:05:52

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.

US3232056

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 13:41:45

Generated On: 09 Jun 2021 16:05:52

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 11 MAR 2021

What was the treatment time? (00:00-23:59) 08:48 (24 HR)

Treatment Date and Time (derived) 11 MAR 2021 08:48

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

US3232056

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 13:41:45

Generated On: 09 Jun 2021 16:05:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232056

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 13:42:12

Generated On: 09 Jun 2021 16:05:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3232056

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 13:42:12

Generated On: 09 Jun 2021 16:05:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232056

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:52

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 _____

US3232056

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

| | |
|-------------------------------------------|-----------------------------------|
| Were vital signs assessed? | Yes <input type="checkbox"/> |
| | No <input type="checkbox"/> |
| 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="checkbox"/> |
| | Axillary <input type="checkbox"/> |
| | Other <input type="checkbox"/> |
| 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 | |
| Height (derived) | |
| Weight (derived) | |

US3232056

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:52

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.

US3232056

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:52

Was the sample collected?

Yes ☐

No ☐

Collection date (*dd MMM yyyy*)

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

Collection date and time (derived)

US3232056

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 19:53:10

Generated On: 09 Jun 2021 16:05:52

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3232056

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 15:21:02

Generated On: 09 Jun 2021 16:05:52

AEID

Adverse event

PANSINUSITIS

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)

30 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

03 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

522 of 4306

EAB) (1725)

US3232056

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 15:21:02

Generated On: 09 Jun 2021 16:05:52

| | |
|---------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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) | _____ |

US3232056

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Apr 2021 15:21:02

Generated On: 09 Jun 2021 16:05:52

AEID

Adverse event

SORE THROAT

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)

30 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

03 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

524 of 4306

EAB) (1725)

US3232056

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Apr 2021 15:21:02

Generated On: 09 Jun 2021 16:05:52

| | |
|---------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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) | _____ |

US3232056

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Apr 2021 15:21:02

Generated On: 09 Jun 2021 16:05:52

| | |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID | USA-US105-2021-MRNA-1273-P30 1000002 |
| Adverse event | COVID-19 |
| 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 checked="" type="radio"/> No <input type="radio"/> |
| Start date (dd MMM yyyy) | 02 JAN 2021 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | 21 JAN 2021 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | False |
| Hospital Admission Date (dd MMM yyyy) | |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |

PRODUCTION RELEASE (v12.003
EAB) (1725)

526 of 4306

US3232056

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Apr 2021 15:21:02

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 23 Apr 2021 15:21:02

Generated On: 09 Jun 2021 16:05:52

| | |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID | USA-US105-2021-MRNA-1273-P30 1000002 |
| Adverse event | SYNCOPE |
| 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) | 16 JAN 2021 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | 19 JAN 2021 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | True |
| Hospital Admission Date (dd MMM yyyy) | 16 JAN 2021 |
| Hospital Discharge Date (dd MMM yyyy) | 19 JAN 2021 |
| Admitted to ICU? | Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/> |

PRODUCTION RELEASE (v12.003
EAB) (1725)

528 of 4306

US3232056

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 23 Apr 2021 15:21:02

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 23 Apr 2021 15:21:02

Generated On: 09 Jun 2021 16:05:52

SUBJECT WAS ADMITTED BY
AMBULANCE TO ST DOMINICS
HOSPITAL IN JACKSON MS
16JAN2021 DUE TO SYNCOPE
RELATED TO INTERMITTENT
COMPLETE HEART BLOCK.
WHILE RIDING AS A
PASSENGER IN AN
AUTOMOBILE SUBJECT
EXPERIENCED INTERMITTENT
ALTERED CONSCIOUS AND
SYNCOPE. THE DRIVER PULLED
OVER AND SUMMONED AN
AMBULANCE. PATIENT HAD A
PMH SIGNIFICANT FOR
CARDIOMYOPATHY AND HTN
WAS TAKING A BETA
BLOCKER. SUBJECT HAD A
PACEMAKER PLACED ON
18JAN2021 AND WAS
DISCHARGED ON 19JAN2021.
SUBJECT HAD RECENT COVID
INFECTION 8JAN2021.
INVESTIGATOR DOES NOT
THINK SUBJECT'S SYNCOPE OR
HEART BLOCK WAS RELATED
TO IP SINCE SHE HAD A
KNOWN HISTORY OF
CHF/CARDIOMYOPATHY AND
WAS TAKING A BETA BLOCKER

| | |
|------------------------------------------------------------|---|
| 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 |

US3232056

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 23 Apr 2021 15:21:02

Generated On: 09 Jun 2021 16:05:52

| | |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID | USA-US105-2021-MRNA-1273-P30 1000002 |
| Adverse event | COMPLETE HEART BLOCKAGE |
| 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) | 16 JAN 2021 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | 19 JAN 2021 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | True |
| Hospital Admission Date (dd MMM yyyy) | 16 JAN 2021 |
| Hospital Discharge Date (dd MMM yyyy) | 19 JAN 2021 |
| Admitted to ICU? | Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/> |

PRODUCTION RELEASE (v12.003
EAB) (1725)

531 of 4306

US3232056

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 23 Apr 2021 15:21:02

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 23 Apr 2021 15:21:02

Generated On: 09 Jun 2021 16:05:52

SUBJECT WAS ADMITTED BY
AMBULANCE TO ST DOMINICS
HOSPITAL IN JACKSON MS
16JAN2021 DUE TO SYNCOPE
RELATED TO INTERMITTENT
COMPLETE HEART BLOCK.
WHILE RIDING AS A
PASSENGER IN AN
AUTOMOBILE SUBJECT
EXPERIENCED INTERMITTENT
ALTERED CONSCIOUS AND
SYNCOPE. THE DRIVER PULLED
OVER AND SUMMONED AN
AMBULANCE. PATIENT HAD A
PMH SIGNIFICANT FOR
CARDIOMYOPATHY AND HTN
WAS TAKING A BETA
BLOCKER. SUBJECT HAD A
PACEMAKER PLACED ON
18JAN2021 AND WAS
DISCHARGED ON 19JAN2021.
SUBJECT HAD RECENT COVID
INFECTION 8JAN2021.
INVESTIGATOR DOES NOT
THINK SUBJECT'S SYNCOPE OR
HEART BLOCK WAS RELATED
TO IP SINCE SHE HAD A
KNOWN HISTORY OF
CHF/CARDIOMYOPATHY AND
WAS TAKING A BETA BLOCKER

| | |
|------------------------------------------------------------|---|
| 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 |

US3232056

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 23 Apr 2021 15:21:02

Generated On: 09 Jun 2021 16:05:52

| | |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID | |
| Adverse event | SINUSITIS |
| Was this a medically-attended AE? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Was this a Solicited Adverse Reaction? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Is this event a confirmed diagnosis of Symptomatic Covid-19? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Start date (dd MMM yyyy) | 09 APR 2021 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | False |
| Hospital Admission Date (dd MMM yyyy) | |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |
| Number of Days in ICU | |

PRODUCTION RELEASE (v12.003
EAB) (1725)

534 of 4306

US3232056

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 23 Apr 2021 15:21:02

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 23 Apr 2021 15:21:02

Generated On: 09 Jun 2021 16:05:52

| | |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID | |
| Adverse event | FATIGUE |
| Was this a medically-attended AE? | Yes <input type="radio"/> No <input checked="" 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) | 02 APR 2021 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | 17 APR 2021 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | False |
| Hospital Admission Date (dd MMM yyyy) | |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |
| Number of Days in ICU | |

PRODUCTION RELEASE (v12.003
EAB) (1725)

536 of 4306

US3232056

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 23 Apr 2021 15:21:02

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 23 Apr 2021 15:21:02

Generated On: 09 Jun 2021 16:05:52

| | |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID | |
| Adverse event | HEADACHE |
| 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) | 11 APR 2021 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | 17 APR 2021 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | False |
| Hospital Admission Date (dd MMM yyyy) | |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |
| Number of Days in ICU | |

PRODUCTION RELEASE (v12.003
EAB) (1725)

538 of 4306

US3232056

Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 23 Apr 2021 15:21:02

Generated On: 09 Jun 2021 16:05:52

| | |
|---------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Action taken with investigational product | None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/> |
| Other action taken (check all that apply) | |
| None | False |
| Concomitant Medication | True |
| Concomitant Procedure | 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) | _____ |

US3232056

Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 23 Apr 2021 15:21:02

Generated On: 09 Jun 2021 16:05:52

AEID

Adverse event

NASAL CONGESTION

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)

11 APR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

17 APR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

540 of 4306

EAB) (1725)

US3232056

Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 23 Apr 2021 15:21:02

Generated On: 09 Jun 2021 16:05:52

| | |
|---------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Action taken with investigational product | None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/> |
| Other action taken (check all that apply) | |
| None | False |
| Concomitant Medication | True |
| Concomitant Procedure | 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) | _____ |

US3232056

Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) 23 Apr 2021 15:21:02

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) 23 Apr 2021 15:21:02

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: Adverse Events

Form: Adverse Events (14)

Data signed: (b) (4) 23 Apr 2021 15:21:02

Generated On: 09 Jun 2021 16:05:52

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

544 of 4306

US3232056

Folder: Adverse Events

Form: Adverse Events (14)

Data signed: (b) (4) 23 Apr 2021 15:21:02

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: Adverse Events

Form: Adverse Events (15)

Data signed: (b) (4) 23 Apr 2021 15:21:02

Generated On: 09 Jun 2021 16:05:52

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

546 of 4306

US3232056

Folder: Adverse Events

Form: Adverse Events (15)

Data signed: (b) (4) 23 Apr 2021 15:21:02

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: Adverse Events

Form: Adverse Events (16)

Data signed: (b) (4) 23 Apr 2021 15:21:02

Generated On: 09 Jun 2021 16:05:52

| | |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID | |
| Adverse event | FATIGUE |
| Was this a medically-attended AE? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Was this a Solicited Adverse Reaction? | Yes <input checked="" type="radio"/> No <input 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) | 28 AUG 2020 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | False |
| Hospital Admission Date (dd MMM yyyy) | |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |
| Number of Days in ICU | |

PRODUCTION RELEASE (v12.003
EAB) (1725)

548 of 4306

US3232056

Folder: Adverse Events

Form: Adverse Events (16)

Data signed: (b) (4) 23 Apr 2021 15:21:02

Generated On: 09 Jun 2021 16:05:52

| | |
|------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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 type="radio"/> Related <input checked="" 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 | True |
| Concomitant Medication | False |
| Concomitant Procedure | False |
| Outcome | Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| <hr/> | |
| Narrative | |
| <hr/> | |
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 0 |
| Admitted to ICU Derived (CSA Programming Field Only) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 13:41:43

Generated On: 09 Jun 2021 16:05:52

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

Yes ☒

No ☐

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

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 2.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

551 of 4306

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------------------------------------|--------------------------|----------------------------------|
| | 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) | 6 AUG 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PROPHYLACTIC

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)

553 of 4306

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------------------------------------|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2019 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 108

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)

555 of 4306

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

Name of Medication BREO ELLIPTA 100/25

Prophylaxis Yes ☐
No ☒

Indication ASTHMA/ COPD

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

557 of 4306

EAB) (1725)

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------------------------------------|--------------------------|----------------------------------|
| | Intramuscular | <input type="radio"/> |
| | Respiratory (Inhalation) | <input checked="" type="radio"/> |
| | Intralesional | <input type="radio"/> |
| | Intraperitoneal | <input type="radio"/> |
| | Nasal | <input type="radio"/> |
| | Vaginal | <input type="radio"/> |
| | Rectal | <input type="radio"/> |
| | Intravenous | <input type="radio"/> |
| | Intravenous Bolus | <input type="radio"/> |
| | Intravenous Drip | <input type="radio"/> |
| | Other | <input type="radio"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2017 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

Name of Medication CARVEDILOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

559 of 4306

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------------------------------------|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2019 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

Name of Medication CHOLECALCIFEROL (VITAMIN D3)

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

561 of 4306

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

| | | |
|------------------------------------------------|--------------------------|----------------------------------|
| | Intraocular | <input type="checkbox"/> |
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify | | |
| Start date (dd MMM yyyy) | UN | UNK 2019 |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

Name of Medication FLUOXETINE

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

563 of 4306

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------------------------------------|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | 12 MAR 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 2 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROID

Dose per administration 50

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

If dose unit is Other, specify MCG

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)

565 of 4306

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------------------------------------|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN | UNK 2019 |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

Name of Medication CYANOCOBATAMIN

Prophylaxis Yes ☐
No ☒

Indication B12 DEFICIENCY

Dose per administration 1000

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

If dose unit is Other, specify MCG

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

567 of 4306

EAB) (1725)

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

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

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

Name of Medication FERROUS SULFATE

Prophylaxis Yes ☐
No ☒

Indication ANEMIA

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

569 of 4306

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------------------------------------|--------------------------|----------------------------------|
| | 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 1994 |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

Name of Medication CEFDINIR

Prophylaxis Yes ☐
No ☒

Indication PANSINUSITIS

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)

571 of 4306

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------------------------------------|--------------------------|-------------------------------------|
| | 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) | | 30 SEP 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 10 OCT 2020 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | | 2 |
| Interval Dosage Unit Number (derived) | | 1 |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input checked="" type="checkbox"/> |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

Name of Medication ZINC

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 100

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

573 of 4306

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------------------------------------|--------------------------|----------------------------------|
| | 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 JAN 2021 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐
No ☒

Indication COVID-19

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)

575 of 4306

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------------------------------------|--------------------------|-------------------------------------|
| | 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 JAN 2021 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 08 JAN 2021 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input checked="" type="checkbox"/> |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 250

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

577 of 4306

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------------------------------------|--------------------------|-------------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | 09 JAN 2021 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | 12 JAN 2021 | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input checked="" type="checkbox"/> |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

Name of Medication VITAMIN D3

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 200

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

579 of 4306

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------------------------------------|--------------------------|----------------------------------|
| | 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 JAN 2021 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

Name of Medication VITAMIN C

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 1000

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

581 of 4306

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------------------------------------|--------------------------|----------------------------------|
| | 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 JAN 2021 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

Name of Medication MELATONIN

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 5

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

583 of 4306

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------------------------------------|--------------------------|----------------------------------|
| | 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 JAN 2021 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

Name of Medication NATTOKINASE

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 200

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

585 of 4306

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------------------------------------|--------------------------|----------------------------------|
| | 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 JAN 2021 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

Name of Medication EXTRA STRENGTH EXCEDRIN
(ACETAMINOPHEN/CAFFIENE)

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 500/130

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)

587 of 4306

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------------------------------------|--------------------------|----------------------------------|
| | 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) | | 13 JAN 2021 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | | 1 |
| Interval Dosage Unit Number (derived) | | 1 |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

Name of Medication NARCAN

Prophylaxis Yes ☐
No ☒

Indication SYNCOPE

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)

589 of 4306

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------------------------------------|--------------------------|-------------------------------------|
| | 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) | | 16 JAN 2021 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 16 JAN 2021 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

Name of Medication DOXYCYCLINE HYCLATE

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS BACTERIA
INFECTION

Dose per administration 100

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

591 of 4306

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------------------------------------|--------------------------|----------------------------------|
| | 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) | | 19 JAN 2021 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | | 2 |
| Interval Dosage Unit Number (derived) | | 1 |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 400

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)

593 of 4306

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------------------------------------|--------------------------|-------------------------------------|
| | 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) | 27 JAN 2021 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) 27 JAN 2021 | | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input checked="" type="checkbox"/> |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

Name of Medication SODIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication SYNCOPE

Dose per administration 10

Dose unit mg ☐
ug ☐
mL ☒
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

595 of 4306

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------------------------------------|-----------------------------------------|-------------------------------------|
| | 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) | 16 JAN 2021 | |
| Start date completely unknown | False | |
| Ongoing? | Yes <input type="checkbox"/> | |
| | No <input checked="" type="checkbox"/> | |
| If not Ongoing, End date (dd MMM yyyy) | 16 JAN 2021 | |
| Was this medication taken for solicited event? | Yes <input type="checkbox"/> | |
| | No <input checked="" type="checkbox"/> | |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 <input type="checkbox"/> | |
| | 803 <input type="checkbox"/> | |
| | 804 <input checked="" type="checkbox"/> | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 10

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

597 of 4306

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------------------------------------|--------------------------|-------------------------------------|
| | 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) | 16 JAN 2021 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | 02 FEB 2021 | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input checked="" type="checkbox"/> |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 10

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

599 of 4306

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------------------------------------|--------------------------|----------------------------------|
| | 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) | 16 JAN 2021 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 5

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

601 of 4306

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------------------------------------|--------------------------|----------------------------------|
| | 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) | | 03 FEB 2021 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | | 1 |
| Interval Dosage Unit Number (derived) | | 1 |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

Name of Medication ONDANSETRON

Prophylaxis Yes ☒
No ☐

Indication NAUSEA PROPHYLAXIS

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)

603 of 4306

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------------------------------------|--------------------------------------|----------------------------------|
| | Intramuscular | <input type="radio"/> |
| | Respiratory (Inhalation) | <input type="radio"/> |
| | Intralesional | <input type="radio"/> |
| | Intraperitoneal | <input type="radio"/> |
| | Nasal | <input type="radio"/> |
| | Vaginal | <input type="radio"/> |
| | Rectal | <input type="radio"/> |
| | Intravenous | <input checked="" 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) | 16 JAN 2021 | |
| Start date completely unknown | False | |
| Ongoing? | Yes <input type="radio"/> | |
| | No <input checked="" type="radio"/> | |
| If not Ongoing, End date (dd MMM yyyy) | 16 JAN 2021 | |
| Was this medication taken for solicited event? | Yes <input type="radio"/> | |
| | No <input checked="" type="radio"/> | |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 <input type="radio"/> | |
| | 803 <input type="radio"/> | |
| | 804 <input checked="" type="radio"/> | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication PRE/POST OPERATIVE PAIN
(SURGICAL SITE-PACEMAKER)

Dose per administration 1300

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)

605 of 4306

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

| | | |
|------------------------------------------------|--------------------------|-------------------------------------|
| | 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) | 16 JAN 2021 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | 19 JAN 2021 | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input checked="" type="checkbox"/> |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

Name of Medication DOCUSATE COLACE

Prophylaxis Yes ☒
No ☐

Indication PROPHYLACTIC CONSTIPATION

Dose per administration 100

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

607 of 4306

EAB) (1725)

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------------------------------------|--------------------------|-------------------------------------|
| | 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) | 16 JAN 2021 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 19 JAN 2021 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input checked="" type="checkbox"/> |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

Name of Medication PROMETHAZINE

Prophylaxis Yes ☒
No ☐

Indication PROPHYLACTIC N//V

Dose per administration 12.5

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

609 of 4306

EAB) (1725)

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------------------------------------|--------------------------|----------------------------------|
| | Intramuscular | <input type="radio"/> |
| | Respiratory (Inhalation) | <input type="radio"/> |
| | Intralesional | <input type="radio"/> |
| | Intraperitoneal | <input type="radio"/> |
| | Nasal | <input type="radio"/> |
| | Vaginal | <input type="radio"/> |
| | Rectal | <input type="radio"/> |
| | Intravenous | <input checked="" 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) | 17 JAN 2021 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 17 JAN 2021 |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

Name of Medication CHLORHEXIDINE 2%

Prophylaxis Yes ☒
No ☐

Indication PROPHYLACTIC FOR INFECTION

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify APPLICATION

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)

611 of 4306

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

| | | |
|------------------------------------------------|--------------------------|-------------------------------------|
| | 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) | 17 JAN 2021 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 18 JAN 2021 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input checked="" type="checkbox"/> |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

Name of Medication DOXYCYCLINE

Prophylaxis Yes ☐
No ☒

Indication SINUSITIS

Dose per administration 100

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

613 of 4306

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 23 Apr 2021 15:21:04

Generated On: 09 Jun 2021 16:05:52

| | | |
|----------------------------------------------------|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | 15 APR 2021 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 2 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3232056

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 13:41:43

Generated On: 09 Jun 2021 16:05:52

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3232056

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 02 Apr 2021 13:41:43

Generated On: 09 Jun 2021 16:05:52

| Procedure/Surgery date (dd MMM yyyy) | Procedure/Surgery | Indication | If indication is Other, specify |
|-----------------------------------------|---------------------|---------------|---------------------------------|
| 18 JAN 2021 | PACEMAKER PLACEMENT | Adverse Event | |

US3232056

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 16:05:52

| | | |
|-------|-----------------|--------------------------|
| Visit | Screening | <input type="checkbox"/> |
| | Visit 1 Day 1 | <input type="checkbox"/> |
| | Visit 2 Day 29 | <input type="checkbox"/> |
| | Visit 3 Day 57 | <input type="checkbox"/> |
| | Visit 4 Day 209 | <input type="checkbox"/> |
| | Visit 5 Day 394 | <input type="checkbox"/> |
| | Visit 6 Day 759 | <input type="checkbox"/> |

Case Report Form

| | |
|----------------------------------------------------------------------------|--|
| Visit Date | |
| Demographics | |
| Enrollment | |
| Inclusion/Exclusion Criteria Summary | |
| Inclusion/Exclusion Criteria | |
| Medical History Summary | |
| Medical History | |
| Vital Signs | |
| Vital Signs - Dosing | |
| Physical Examination | |
| Central Laboratory - Nasopharyngeal Swab | |
| Childbearing Potential | |
| Pregnancy Test | |
| Randomization | |
| Exposure | |
| Immunogenicity Assessment | |
| Saliva Collection | |
| COVID Diagnostic Test | |
| Symptom Log | |
| Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection | |
| COVID-19 Severity Assessment | |
| COVID-19 Contact | |
| Risk of Exposure | |
| Safety Call | |
| Dosing Discontinuation | |
| End of Study / Study Discontinuation | |

US3232056

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 09 Jun 2021 16:05:52

| | |
|-----------------------------------------------------|--|
| All | |
| Date of missed or out of window visit or assessment | |
| Category | |
| Inclusion criteria not met/Exclusion criteria met | |
| Study Treatment not given | |
| Missed Visit | |
| Missed Assessment | |
| Visit performed out of window | |
| Assessment performed out of window | |
| Scheduled clinical visit performed as home visit | |
| Other | |
| Other, specify | |
| Description of Relationship to COVID-19 | |
| Clinical site closed | |
| Travel restrictions | |
| Quarantine due to COVID-19 | |
| Possible exposure to COVID-19 | |
| Exposure to COVID-19 | |
| Presumption / confirmed COVID-19 | |
| Symptoms of COVID-19 | |
| Sponsor hold due to COVID-19 | |
| Participant decision | |

US3232056

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:05:52

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3232056

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:05:52

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 ☐

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 02 Apr 2021 13:41:46

Generated On: 09 Jun 2021 16:05:52

| | |
|----------------------------------------------------------------|------------------------------------------------------------------|
| SAEID | USA-US105-2021-MRNA-1273-P301000002 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | RAMBOD |
| Investigator's Last Name | ROUHBAKHSH |
| Site Address: Street | MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC |
| Site Address: City | PETAL |
| Site Address: State | MS |
| Site Address: Postal Code | 39465 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 5 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 02 Apr 2021 13:41:46

Generated On: 09 Jun 2021 16:05:52

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID | USA-US105-2021-MRNA-1273-P301000002 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | RAMBOD |
| Investigator's Last Name | ROUHBAKHSH |
| Site Address: Street | MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC |
| Site Address: City | PETAL |
| Site Address: State | MS |
| Site Address: Postal Code | 39465 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 5 |
| Date of submission (Pre-filled from custom function) | 13/JAN/2021 12:48 |
| 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 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 02 Apr 2021 13:41:46

Generated On: 09 Jun 2021 16:05:52

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID | USA-US105-2021-MRNA-1273-P301000002 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | RAMBOD |
| Investigator's Last Name | ROUHBAKHSH |
| Site Address: Street | MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC |
| Site Address: City | PETAL |
| Site Address: State | MS |
| Site Address: Postal Code | 39465 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 5 |
| Date of submission (Pre-filled from custom function) | 17/FEB/2021 16:41 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 02 Apr 2021 13:41:46

Generated On: 09 Jun 2021 16:05:52

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID | USA-US105-2021-MRNA-1273-P301000002 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | RAMBOD |
| Investigator's Last Name | ROUHBAKHSH |
| Site Address: Street | MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC |
| Site Address: City | PETAL |
| Site Address: State | MS |
| Site Address: Postal Code | 39465 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 5 |
| Date of submission (Pre-filled from custom function) | 23/FEB/2021 14:16 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) 02 Apr 2021 13:41:46

Generated On: 09 Jun 2021 16:05:52

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID | USA-US105-2021-MRNA-1273-P301000002 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | RAMBOD |
| Investigator's Last Name | ROUHBAKHSH |
| Site Address: Street | MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC |
| Site Address: City | PETAL |
| Site Address: State | MS |
| Site Address: Postal Code | 39465 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 5 |
| Date of submission (Pre-filled from custom function) | 05/MAR/2021 09:39 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form (5)

Data signed: (b) (4) 02 Apr 2021 13:41:46

Generated On: 09 Jun 2021 16:05:52

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID | USA-US105-2021-MRNA-1273-P301000002 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | RAMBOD |
| Investigator's Last Name | ROUHBAKHSH |
| Site Address: Street | MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC |
| Site Address: City | PETAL |
| Site Address: State | MS |
| Site Address: Postal Code | 39465 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 5 |
| Date of submission (Pre-filled from custom function) | 16/MAR/2021 09:29 |
| 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. | True |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 02 Apr 2021 13:41:46

Generated On: 09 Jun 2021 16:05:52

| | |
|----------------------------------------------------------------|------------------------------------------------------------------|
| SAEID | USA-US105-2021-MRNA-1273-P301000003 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | RAMBOD |
| Investigator's Last Name | ROUHBAKHSH |
| Site Address: Street | MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC |
| Site Address: City | PETAL |
| Site Address: State | MS |
| Site Address: Postal Code | 39465 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 4 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 02 Apr 2021 13:41:46

Generated On: 09 Jun 2021 16:05:52

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID | USA-US105-2021-MRNA-1273-P301000003 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | RAMBOD |
| Investigator's Last Name | ROUHBAKHSH |
| Site Address: Street | MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC |
| Site Address: City | PETAL |
| Site Address: State | MS |
| Site Address: Postal Code | 39465 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 4 |
| Date of submission (Pre-filled from custom function) | 21/JAN/2021 14:17 |
| 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 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 02 Apr 2021 13:41:46

Generated On: 09 Jun 2021 16:05:52

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID | USA-US105-2021-MRNA-1273-P301000003 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | RAMBOD |
| Investigator's Last Name | ROUHBAKHSH |
| Site Address: Street | MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC |
| Site Address: City | PETAL |
| Site Address: State | MS |
| Site Address: Postal Code | 39465 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 4 |
| Date of submission (Pre-filled from custom function) | 25/JAN/2021 15:08 |
| 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 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 02 Apr 2021 13:41:46

Generated On: 09 Jun 2021 16:05:52

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID | USA-US105-2021-MRNA-1273-P301000003 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | RAMBOD |
| Investigator's Last Name | ROUHBAKHSH |
| Site Address: Street | MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC |
| Site Address: City | PETAL |
| Site Address: State | MS |
| Site Address: Postal Code | 39465 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 4 |
| Date of submission (Pre-filled from custom function) | 12/FEB/2021 12:51 |
| 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 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 02 Apr 2021 13:41:46

Generated On: 09 Jun 2021 16:05:52

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID | USA-US105-2021-MRNA-1273-P301000003 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | RAMBOD |
| Investigator's Last Name | ROUHBAKHSH |
| Site Address: Street | MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC |
| Site Address: City | PETAL |
| Site Address: State | MS |
| Site Address: Postal Code | 39465 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 4 |
| Date of submission (Pre-filled from custom function) | 12/FEB/2021 14:29 |
| 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. | True |

Audit

US3232056 (Prod: MediSync Clinical Research Hattiesburg Clinic)

US3232056

Form: Participant Creation

Generated On: 09 Jun 2021 16:05:52

[Participant ID](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'US3232056' | RWS_ENDPOINT | 17 Aug 2020 14:24:37 |
| | ENDPOINT (b) (4) | |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:05:52

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:31:28 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:05:52

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '17 AUG 2020' | RWS_ENDPOINT | 17 Aug 2020 14:24:38 |
| | ENDPOINT (b) (4) | |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:05:52

Was visit performed at the participant's home or at the clinic?

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Clinic (Clinic)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:31:28 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:05:52

[Folder OID](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered 'SCRN' | (b) (4), (b) (6) System | 18 Aug 2020 12:31:28 |

US3232056

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:52

Date of Birth (MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered (b) (6) 1948' | RWS_ENDPOINT | 17 Aug 2020 14:24:39 |
| | ENDPOINT (b) (4) | |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:52

[Age](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '72' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:31:58 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:52

[Age Units](#)

| Audit | User | Time (GMT) |
|----------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered 'YEARS' | (b) (4), (b) (6) System | 18 Aug 2020 12:31:58 |

US3232056

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:52

[Age \(Derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered '72' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:21 |

US3232056

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:52

Sex

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Female (F)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:31:58 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:52

[Ethnicity](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:31:58 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:52

White

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'I' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:31:58 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:52

Black

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:31:58 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:52

[Asian](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:31:58 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:52

[American Indian or Alaska Native](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:31:58 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:52

[Native Hawaiian or other Pacific Islander](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:31:58 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:52

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:31:58 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:52

If race is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:31:58 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:52

Unknown

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:31:58 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:52

Not reported

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:31:58 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:52

Date of Informed Consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '17 Aug 2020' | Jerrica Sullivan (b) (4) | 17 Aug 2020 16:23:21 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:52

[Month and Year of Informed Consent \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered 'Aug 2020' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:21 |

US3232056

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:52

[Year of Informed Consent \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered '2020' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:21 |

US3232056

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:52

[Protocol Version](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Amendment 2 (2)' | Jerrica Sullivan (b) (4) | 17 Aug 2020 16:23:21 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:52

[Was participant enrolled in the study?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 17 Aug 2020 16:23:21 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:52

[If No, indicate reason for screen fail](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 17 Aug 2020 16:23:21 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:52

If reason for screen fail is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 17 Aug 2020 16:23:21 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:52

[Was this participant screened previously?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 17 Aug 2020 16:23:21 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:52

[If Yes, previous participant number](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered empty. | RWS_ENDPOINT | 17 Aug 2020 14:24:38 |
| | ENDPOINT (b) (4) | |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:52

[Enrollment Trigger](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered 'I' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:31 |

US3232056

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:05:52

[Did the participant meet all eligibility criteria?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 17 Aug 2020 16:23:31 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:05:52

[Were any significant conditions reported?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:32:30 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:52

Condition

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Wheezing, LLT: Asthmatic wheezing - version MedDRA\\23.0. | Coder Import (b) (4) | 18 Aug 2020 15:00:22 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 18 Aug 2020 15:00:22 |
| | (b) (4) | |
| Data point term sent to Coder | System | 18 Aug 2020 12:34:16 |
| User entered 'asthma/wheezing' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:34:09 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:52

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'un UNK 2017' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:34:09 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:52

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:34:09 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:52

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:34:09 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:52

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:34:09 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:52

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:34:09 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:52

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered 'Jan 2017' | (b) (4), (b) (6) System | 18 Aug 2020 12:34:09 |

US3232056

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:52

[Start Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered '2017' | (b) (4), (b) (6) System | 18 Aug 2020 12:34:09 |

US3232056

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:52

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered empty. | (b) (4), (b) (6) System | 18 Aug 2020 12:34:09 |

US3232056

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:52

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered empty. | (b) (4), (b) (6) System | 18 Aug 2020 12:34:09 |

US3232056

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:52

Condition

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD - version MedDRA\\23.0. | Coder Import (b) (4) | 02 Sep 2020 18:56:09 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 02 Sep 2020 18:56:09 |
| | (b) (4) | |
| Data point term sent to Coder | System | 02 Sep 2020 18:55:17 |
| User closed query 'CDM-Coding: Please either provide a single clinical diagnosis for this reported event or split to report each event separately to capture coding for all terms. Example: 1) COPD 2) EMPHYSEMA | System | 02 Sep 2020 18:54:41 |
| ' (Site from System). | | |
| Query 'CDM-Coding: Please either provide a single clinical diagnosis for this reported event or split to report each event separately to capture coding for all terms. Example: 1) COPD 2) EMPHYSEMA | Jerrica Sullivan (b) (4) | 02 Sep 2020 18:54:41 |
| ' answered with 'corrected' (Site from System). | (b) (4) | |
| User entered 'COPD' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) | 02 Sep 2020 18:54:35 |
| | (b) (4) | |
| User opened query 'CDM-Coding: Please either provide a single clinical diagnosis for this reported event or split to report each event separately to capture coding for all terms. Example: 1) COPD 2) EMPHYSEMA | Coder Import (b) (4) | 02 Sep 2020 08:35:36 |
| | (b) (4) | |
| ' (Site from System). | | |
| Data point term sent to Coder | System | 19 Aug 2020 12:36:23 |
| User closed query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System). | System | 19 Aug 2020 12:36:18 |
| Query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' answered with 'subject has copd only ' (Site from System). | Jerrica Sullivan (b) (4) | 19 Aug 2020 12:36:18 |
| | (b) (4) | |
| User entered 'COPD EMPHYSEMA' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) | 19 Aug 2020 12:36:00 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:52

[Condition](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User opened query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System). | Coder Import (b) (4) | 18 Aug 2020 16:21:04 |
| Data point term sent to Coder | System | 18 Aug 2020 12:35:16 |
| User entered 'COPD Emphysema/Chronic Bronchitis' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:35:09 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:52

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'un UNK 2017' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:35:09 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:52

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:35:09 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:52

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:35:09 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:52

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:35:09 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:52

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:35:09 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:52

[Start Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered 'Jan 2017' | (b) (4), (b) (6) System | 18 Aug 2020 12:35:09 |

US3232056

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:52

[Start Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered '2017' | (b) (4), (b) (6) System | 18 Aug 2020 12:35:09 |

US3232056

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:52

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered empty. | (b) (4), (b) (6) System | 18 Aug 2020 12:35:09 |

US3232056

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:52

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered empty. | (b) (4), (b) (6) System | 18 Aug 2020 12:35:09 |

US3232056

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:52

[Condition](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\\23.0. | Coder Import (b) (4) | 18 Aug 2020 12:38:24 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 18 Aug 2020 12:38:24 |
| | (b) (4) | |
| Data point term sent to Coder | System | 18 Aug 2020 12:37:21 |
| User entered 'Sleep apnea' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:36:24 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:52

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'un UNK 2018' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:36:24 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:52

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:36:24 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:52

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:36:24 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:52

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:36:24 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:52

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:36:24 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:52

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered 'Jan 2018' | (b) (4), (b) (6) System | 18 Aug 2020 12:36:24 |

US3232056

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:52

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered '2018' | (b) (4), (b) (6) System | 18 Aug 2020 12:36:24 |

US3232056

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:52

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered empty. | (b) (4), (b) (6) System | 18 Aug 2020 12:36:24 |

US3232056

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:52

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered empty. | (b) (4), (b) (6) System | 18 Aug 2020 12:36:24 |

US3232056

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:05:52

Condition

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| 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. ' canceled (Site from DM). | (b) (4), (b) (6) | 09 Nov 2020 10:44:52 |
| | (b) (4), (b) (6) | |
| 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) | 11 Sep 2020 14:20:25 |
| | (b) (4), (b) (6) | |
| User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\\23.0. | Coder Import (b) (4) | 18 Aug 2020 12:43:30 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 18 Aug 2020 12:43:30 |
| | (b) (4) | |
| Data point term sent to Coder | System | 18 Aug 2020 12:42:29 |
| User entered 'Congestive Heart Failure' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:41:46 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:05:52

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'un UNK 2019' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:41:46 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:05:52

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:41:46 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:05:52

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:41:46 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:05:52

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:41:46 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:05:52

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:41:46 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:05:52

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered 'Jan 2019' | (b) (4), (b) (6) System | 18 Aug 2020 12:41:46 |

US3232056

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:05:52

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered '2019' | (b) (4), (b) (6) System | 18 Aug 2020 12:41:46 |

US3232056

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:05:52

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered empty. | (b) (4), (b) (6) System | 18 Aug 2020 12:41:46 |

US3232056

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:05:52

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered empty. | (b) (4), (b) (6) System | 18 Aug 2020 12:41:46 |

US3232056

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:05:52

Condition

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| User closed query 'Per CDM: Please review and confirm if this pertains to (#1) 'HYPERTENSION' in the Con Med eCRF? If yes, please reconcile with corresponding CM to maintain consistency among eCRF pages. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 07 Dec 2020 11:17:43 |
| User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 23 Nov 2020 15:55:02 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 23 Nov 2020 15:55:02 |
| Data point term sent to Coder | System | 23 Nov 2020 15:53:44 |
| Query 'Per CDM: Please review and confirm if this pertains to (#1) 'HYPERTENSION' in the Con Med eCRF? If yes, please reconcile with corresponding CM to maintain consistency among eCRF pages. ' answered with 'corrected' (Site from DM). | Jerrica Sullivan (b) (4) (b) (4) | 23 Nov 2020 15:52:58 |
| Coding entries removed. | Jerrica Sullivan (b) (4) (b) (4) | 23 Nov 2020 15:52:51 |
| User entered 'hypertension' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) (b) (4) | 23 Nov 2020 15:52:51 |
| User opened query 'Per CDM: Please review and confirm if this pertains to (#1) 'HYPERTENSION' in the Con Med eCRF? If yes, please reconcile with corresponding CM to maintain consistency among eCRF pages. ' (Site from DM). | (b) (4), (b) (6) (b) (4), (b) (6) | 23 Nov 2020 15:38:06 |
| User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Blood pressure high - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 18 Aug 2020 12:43:27 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 18 Aug 2020 12:43:27 |
| Data point term sent to Coder | System | 18 Aug 2020 12:42:30 |
| User entered 'High blood pressure' | Jerrica Sullivan (b) (4) (b) (4) | 18 Aug 2020 12:42:12 |

US3232056

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:05:52

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'un UNK 2019' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:42:12 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:05:52

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:42:12 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:05:52

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:42:12 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:05:52

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:42:12 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:05:52

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:42:12 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:05:52

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered 'Jan 2019' | (b) (4), (b) (6) System | 18 Aug 2020 12:42:12 |

US3232056

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:05:52

[Start Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered '2019' | (b) (4), (b) (6) System | 18 Aug 2020 12:42:12 |

US3232056

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:05:52

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered empty. | (b) (4), (b) (6) System | 18 Aug 2020 12:42:12 |

US3232056

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:05:52

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered empty. | (b) (4), (b) (6) System | 18 Aug 2020 12:42:12 |

US3232056

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:05:52

Condition

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| Query 'Per DM CLR: Please specify the laterality of TINNITUS (left, right, bilateral). Review and update MH condition as appropriate and ensure update is reconciled with any corresponding ConMed/AE entries, if applicable. | (b) (4), (b) (6) | 05 Nov 2020 20:58:12 |
| ' canceled (Site from DM). | (b) (4), (b) (6) | |
| User opened query 'Per DM CLR: Please specify the laterality of TINNITUS (left, right, bilateral). Review and update MH condition as appropriate and ensure update is reconciled with any corresponding ConMed/AE entries, if applicable. | (b) (4), (b) (6) | 11 Sep 2020 14:24:10 |
| ' (Site from DM). | (b) (4), (b) (6) | |
| User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Tinnitus, LLT: Tinnitus - version MedDRA\\23.0. | Coder Import (b) (4) | 27 Aug 2020 17:45:37 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 27 Aug 2020 17:45:37 |
| | (b) (4) | |
| Data point term sent to Coder | System | 26 Aug 2020 16:29:20 |
| User entered 'tinnitus' | Adreanna Pou (b) (4) | 26 Aug 2020 16:29:04 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:05:52

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '10 Aug 2020' | Adreanna Pou (b) (4) | 26 Aug 2020 16:29:04 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:05:52

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 26 Aug 2020 16:29:04 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:05:52

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 26 Aug 2020 16:29:04 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:05:52

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 16:29:04 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:05:52

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 26 Aug 2020 16:29:04 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:05:52

[Start Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered 'Aug 2020' | (b) (4), (b) (6) System | 26 Aug 2020 16:29:04 |

US3232056

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:05:52

[Start Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered '2020' | (b) (4), (b) (6) System | 26 Aug 2020 16:29:04 |

US3232056

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:05:52

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered empty. | (b) (4), (b) (6) System | 26 Aug 2020 16:29:04 |

US3232056

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:05:52

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered empty. | (b) (4), (b) (6) System | 26 Aug 2020 16:29:04 |

US3232056

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:05:52

[Condition](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Cataracts - version MedDRA\\23.0. | Coder Import (b) (4) | 27 Aug 2020 17:45:48 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 27 Aug 2020 17:45:48 |
| | (b) (4) | |
| Data point term sent to Coder | System | 26 Aug 2020 16:30:21 |
| User entered 'cataracts' | Adreanna Pou (b) (4) | 26 Aug 2020 16:29:25 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:05:52

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'un UNK 2018' | Adreanna Pou (b) (4) | 26 Aug 2020 16:29:25 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:05:52

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 26 Aug 2020 16:29:25 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:05:52

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 26 Aug 2020 16:29:25 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:05:52

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'un UNK 2019' | Adreanna Pou (b) (4) | 26 Aug 2020 16:29:25 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:05:52

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 26 Aug 2020 16:29:25 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:05:52

[Start Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered 'Jan 2018' | (b) (4), (b) (6) System | 26 Aug 2020 16:29:25 |

US3232056

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:05:52

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered '2018' | (b) (4), (b) (6) System | 26 Aug 2020 16:29:25 |

US3232056

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:05:52

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered 'Jan 2019' | (b) (4), (b) (6) System | 26 Aug 2020 16:29:25 |

US3232056

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:05:52

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered '2019' | (b) (4), (b) (6) System | 26 Aug 2020 16:29:25 |

US3232056

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:05:52

Condition

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal spastic and hypermotility disorders, PT: Irritable bowel syndrome, LLT: Irritable bowel syndrome - version MedDRA\\23.0. | Coder Import (b) (4) | 27 Aug 2020 17:46:06 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 27 Aug 2020 17:46:06 |
| | (b) (4) | |
| Data point term sent to Coder | System | 26 Aug 2020 16:32:28 |
| User entered 'irritable bowel syndrome' | Adreanna Pou (b) (4) | 26 Aug 2020 16:31:24 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:05:52

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'un UNK 2010' | Adreanna Pou (b) (4) | 26 Aug 2020 16:31:24 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:05:52

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 26 Aug 2020 16:31:24 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:05:52

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 26 Aug 2020 16:31:24 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:05:52

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 16:31:24 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:05:52

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 26 Aug 2020 16:31:24 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:05:52

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered 'Jan 2010' | (b) (4), (b) (6) System | 26 Aug 2020 16:31:24 |

US3232056

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:05:52

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered '2010' | (b) (4), (b) (6) System | 26 Aug 2020 16:31:24 |

US3232056

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:05:52

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered empty. | (b) (4), (b) (6) System | 26 Aug 2020 16:31:24 |

US3232056

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:05:52

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered empty. | (b) (4), (b) (6) System | 26 Aug 2020 16:31:24 |

US3232056

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:05:52

[Condition](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine headache - version MedDRA\\23.0. | Coder Import (b) (4) | 27 Aug 2020 17:46:06 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 27 Aug 2020 17:46:06 |
| | (b) (4) | |
| Data point term sent to Coder | System | 26 Aug 2020 16:32:29 |
| User entered 'migraine headaches' | Adreanna Pou (b) (4) | 26 Aug 2020 16:32:01 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:05:52

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'un UNK 1956' | Adreanna Pou (b) (4) | 26 Aug 2020 16:32:01 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:05:52

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 26 Aug 2020 16:32:01 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:05:52

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 26 Aug 2020 16:32:01 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:05:52

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 16:32:01 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:05:52

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 26 Aug 2020 16:32:01 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:05:52

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered 'Jan 1956' | (b) (4), (b) (6) System | 26 Aug 2020 16:32:01 |

US3232056

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:05:52

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered '1956' | (b) (4), (b) (6) System | 26 Aug 2020 16:32:01 |

US3232056

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:05:52

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered empty. | (b) (4), (b) (6) System | 26 Aug 2020 16:32:01 |

US3232056

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:05:52

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered empty. | (b) (4), (b) (6) System | 26 Aug 2020 16:32:01 |

US3232056

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:05:52

Condition

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| Query 'Per DM CLR: Please specify the location of SHINGLES. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. | (b) (4), (b) (6) | 05 Nov 2020 20:58:18 |
| ' canceled (Site from DM). | (b) (4), (b) (6) | |
| User opened query 'Per DM CLR: Please specify the location of SHINGLES. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. | (b) (4), (b) (6) | 11 Sep 2020 14:24:29 |
| ' (Site from DM). | (b) (4), (b) (6) | |
| User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes zoster, LLT: Shingles - version MedDRA\\23.0. | Coder Import (b) (4) | 27 Aug 2020 17:46:20 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 27 Aug 2020 17:46:20 |
| | (b) (4) | |
| Data point term sent to Coder | System | 26 Aug 2020 16:33:33 |
| User entered 'shingles' | Adreanna Pou (b) (4) | 26 Aug 2020 16:32:36 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:05:52

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'un UNK 1957' | Adreanna Pou (b) (4) | 26 Aug 2020 16:32:36 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:05:52

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 26 Aug 2020 16:32:36 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:05:52

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 26 Aug 2020 16:32:36 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:05:52

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'un UNK 2000' | Adreanna Pou (b) (4) | 26 Aug 2020 16:32:36 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:05:52

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 26 Aug 2020 16:32:36 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:05:52

[Start Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered 'Jan 1957' | (b) (4), (b) (6) System | 26 Aug 2020 16:32:36 |

US3232056

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:05:52

[Start Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered '1957' | (b) (4), (b) (6) System | 26 Aug 2020 16:32:36 |

US3232056

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:05:52

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered 'Jan 2000' | (b) (4), (b) (6) System | 26 Aug 2020 16:32:36 |

US3232056

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:05:52

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered '2000' | (b) (4), (b) (6) System | 26 Aug 2020 16:32:36 |

US3232056

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:05:52

Condition

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| Query 'Per DM CLR: Please specify the type of transfusion and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' canceled (Site from DM). | (b) (4) (b) (4), (b) (6) | 29 Oct 2020 19:11:09 |
| User opened query 'Per DM CLR: Please specify the type of transfusion and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM). | (b) (4), (b) (6) (b) (4), (b) (6) | 11 Sep 2020 14:25:44 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Haematological and lymphoid tissue therapeutic procedures, HLT: Blood and blood product treatment, PT: Transfusion, LLT: Transfusion - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 27 Aug 2020 17:46:23 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 27 Aug 2020 17:46:23 |
| Data point term sent to Coder | System | 26 Aug 2020 16:33:33 |
| User entered 'transfusions' | Adreanna Pou (b) (4) (b) (4) | 26 Aug 2020 16:32:59 |

US3232056

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:05:52

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'un UNK 2015' | Adreanna Pou (b) (4) | 26 Aug 2020 16:32:59 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:05:52

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 26 Aug 2020 16:32:59 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:05:52

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 26 Aug 2020 16:32:59 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:05:52

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'un UNK 2015' | Adreanna Pou (b) (4) | 26 Aug 2020 16:32:59 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:05:52

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 26 Aug 2020 16:32:59 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:05:52

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered 'Jan 2015' | (b) (4), (b) (6) System | 26 Aug 2020 16:32:59 |

US3232056

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:05:52

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered '2015' | (b) (4), (b) (6) System | 26 Aug 2020 16:32:59 |

US3232056

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:05:52

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered 'Jan 2015' | (b) (4), (b) (6) System | 26 Aug 2020 16:32:59 |

US3232056

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:05:52

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered '2015' | (b) (4), (b) (6) System | 26 Aug 2020 16:32:59 |

US3232056

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:05:52

Condition

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| Query 'Per DM CLR: Please specify the laterality of CARPOL TUNNEL SYNDROME (left, right, bilateral). Review and update MH condition as appropriate and ensure update is reconciled with any corresponding ConMed/AE entries, if applicable. ' canceled (Site from DM). | (b) (4), (b) (6) | 05 Nov 2020 20:58:22 |
| | (b) (4), (b) (6) | |
| User opened query 'Per DM CLR: Please specify the laterality of CARPOL TUNNEL SYNDROME (left, right, bilateral). Review and update MH condition as appropriate and ensure update is reconciled with any corresponding ConMed/AE entries, if applicable. ' (Site from DM). | (b) (4), (b) (6) | 11 Sep 2020 14:25:59 |
| | (b) (4), (b) (6) | |
| User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Carpal tunnel syndrome, LLT: Carpal tunnel syndrome - version MedDRA\23.0. | Coder Import (b) (4) | 27 Aug 2020 17:47:08 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) | 27 Aug 2020 17:47:08 |
| | (b) (4) | |
| Data point term sent to Coder | System | 26 Aug 2020 16:34:35 |
| User entered 'carpol tunnel syndrome' | Adreanna Pou (b) (4) | 26 Aug 2020 16:34:17 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:05:52

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'un UNK 2017' | Adreanna Pou (b) (4) | 26 Aug 2020 16:34:17 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:05:52

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 26 Aug 2020 16:34:17 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:05:52

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 26 Aug 2020 16:34:17 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:05:52

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 16:34:17 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:05:52

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 26 Aug 2020 16:34:17 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:05:52

[Start Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered 'Jan 2017' | (b) (4), (b) (6) System | 26 Aug 2020 16:34:17 |

US3232056

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:05:52

[Start Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered '2017' | (b) (4), (b) (6) System | 26 Aug 2020 16:34:17 |

US3232056

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:05:52

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered empty. | (b) (4), (b) (6) System | 26 Aug 2020 16:34:17 |

US3232056

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:05:52

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered empty. | (b) (4), (b) (6) System | 26 Aug 2020 16:34:17 |

US3232056

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:05:52

[Condition](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0. | Coder Import (b) (4) | 27 Aug 2020 17:47:07 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 27 Aug 2020 17:47:07 |
| | (b) (4) | |
| Data point term sent to Coder | System | 26 Aug 2020 16:35:36 |
| User entered 'depression' | Adreanna Pou (b) (4) | 26 Aug 2020 16:34:42 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:05:52

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '02 Mar 2020' | Adreanna Pou (b) (4) | 26 Aug 2020 16:34:42 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:05:52

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 26 Aug 2020 16:34:42 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:05:52

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 26 Aug 2020 16:34:42 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:05:52

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 16:34:42 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:05:52

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 26 Aug 2020 16:34:42 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:05:52

[Start Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered 'Mar 2020' | (b) (4), (b) (6) System | 26 Aug 2020 16:34:42 |

US3232056

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:05:52

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered '2020' | (b) (4), (b) (6) System | 26 Aug 2020 16:34:42 |

US3232056

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:05:52

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered empty. | (b) (4), (b) (6) System | 26 Aug 2020 16:34:42 |

US3232056

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:05:52

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered empty. | (b) (4), (b) (6) System | 26 Aug 2020 16:34:42 |

US3232056

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:05:52

[Condition](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| 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) | 27 Aug 2020 17:47:03 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 27 Aug 2020 17:47:03 |
| | (b) (4) | |
| Data point term sent to Coder | System | 26 Aug 2020 16:36:37 |
| User entered 'anxiety' | Adreanna Pou (b) (4) | 26 Aug 2020 16:35:46 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:05:52

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '02 Mar 2020' | Adreanna Pou (b) (4) | 26 Aug 2020 16:35:46 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:05:52

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 26 Aug 2020 16:35:46 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:05:52

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 26 Aug 2020 16:35:46 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:05:52

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 16:35:46 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:05:52

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 26 Aug 2020 16:35:46 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:05:52

[Start Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered 'Mar 2020' | (b) (4), (b) (6) System | 26 Aug 2020 16:35:46 |

US3232056

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:05:52

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered '2020' | (b) (4), (b) (6) System | 26 Aug 2020 16:35:46 |

US3232056

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:05:52

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered empty. | (b) (4), (b) (6) System | 26 Aug 2020 16:35:46 |

US3232056

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:05:52

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered empty. | (b) (4), (b) (6) System | 26 Aug 2020 16:35:46 |

US3232056

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:05:52

Condition

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms malignant and unspecified (incl nipple), HLT: Breast and nipple neoplasms malignant, PT: Breast cancer, LLT: Breast cancer - version MedDRA\23.0. | Coder Import (b) (4) | 30 Aug 2020 10:24:57 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) | 30 Aug 2020 10:24:57 |
| | (b) (4) | |
| Data point term sent to Coder | System | 29 Aug 2020 12:52:49 |
| User closed query 'DM-Coding: Please provide full name of the procedure/diagnosis to enable proper coding and update this term in accordance with your answer.' (Site from System). | System | 29 Aug 2020 12:52:08 |
| Query 'DM-Coding: Please provide full name of the procedure/diagnosis to enable proper coding and update this term in accordance with your answer.' answered with 'corrected' (Site from System). | Jerrica Sullivan (b) (4) | 29 Aug 2020 12:52:08 |
| | (b) (4) | |
| Data point term sent to Coder | System | 29 Aug 2020 12:51:48 |
| User entered 'BREAST (BILATERAL) cancer' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) | 29 Aug 2020 12:51:40 |
| | (b) (4) | |
| User opened query 'DM-Coding: Please provide full name of the procedure/diagnosis to enable proper coding and update this term in accordance with your answer.' (Site from System). | Coder Import (b) (4) | 28 Aug 2020 09:07:36 |
| | (b) (4) | |
| Data point term sent to Coder | System | 26 Aug 2020 16:36:39 |
| User entered 'breast (bilateral)' | Adreanna Pou (b) (4) | 26 Aug 2020 16:36:27 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:05:52

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'un UNK 1990' | Adreanna Pou (b) (4) | 26 Aug 2020 16:36:27 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:05:52

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 26 Aug 2020 16:36:27 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:05:52

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 26 Aug 2020 16:36:27 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:05:52

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'un UNK 2015' | Adreanna Pou (b) (4) | 26 Aug 2020 16:36:27 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:05:52

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 26 Aug 2020 16:36:27 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:05:52

[Start Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered 'Jan 1990' | (b) (4), (b) (6) System | 26 Aug 2020 16:36:27 |

US3232056

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:05:52

[Start Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered '1990' | (b) (4), (b) (6) System | 26 Aug 2020 16:36:27 |

US3232056

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:05:52

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered 'Jan 2015' | (b) (4), (b) (6) System | 26 Aug 2020 16:36:27 |

US3232056

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:05:52

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered '2015' | (b) (4), (b) (6) System | 26 Aug 2020 16:36:27 |

US3232056

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:05:52

Condition

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\\23.0. | Coder Import (b) (4) | 27 Aug 2020 17:48:01 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 27 Aug 2020 17:48:01 |
| | (b) (4) | |
| Data point term sent to Coder | System | 26 Aug 2020 16:40:47 |
| User entered 'vitamin d deficiency' | Adreanna Pou (b) (4) | 26 Aug 2020 16:39:49 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:05:52

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'un UNK 2019' | Adreanna Pou (b) (4) | 26 Aug 2020 16:39:49 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:05:52

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 26 Aug 2020 16:39:49 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:05:52

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 26 Aug 2020 16:39:49 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:05:52

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 16:39:49 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:05:52

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 26 Aug 2020 16:39:49 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:05:52

[Start Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered 'Jan 2019' | (b) (4), (b) (6) System | 26 Aug 2020 16:39:49 |

US3232056

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:05:52

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered '2019' | (b) (4), (b) (6) System | 26 Aug 2020 16:39:49 |

US3232056

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:05:52

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered empty. | (b) (4), (b) (6) System | 26 Aug 2020 16:39:49 |

US3232056

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:05:52

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered empty. | (b) (4), (b) (6) System | 26 Aug 2020 16:39:49 |

US3232056

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:05:52

[Condition](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0. | Coder Import (b) (4) | 29 Aug 2020 00:31:40 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 29 Aug 2020 00:31:40 |
| | (b) (4) | |
| Data point term sent to Coder | System | 29 Aug 2020 00:30:36 |
| User entered 'hypothyroidism' | Adreanna Pou (b) (4) | 29 Aug 2020 00:30:34 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:05:52

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'un UNK 2019' | Adreanna Pou (b) (4) | 29 Aug 2020 00:30:34 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:05:52

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 29 Aug 2020 00:30:34 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:05:52

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 29 Aug 2020 00:30:34 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:05:52

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 29 Aug 2020 00:30:34 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:05:52

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 29 Aug 2020 00:30:34 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:05:52

[Start Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered 'Jan 2019' | (b) (4), (b) (6) System | 29 Aug 2020 00:30:34 |

US3232056

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:05:52

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered '2019' | (b) (4), (b) (6) System | 29 Aug 2020 00:30:34 |

US3232056

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:05:52

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered empty. | (b) (4), (b) (6) System | 29 Aug 2020 00:30:34 |

US3232056

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:05:52

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered empty. | (b) (4), (b) (6) System | 29 Aug 2020 00:30:34 |

US3232056

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:05:52

Condition

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0. | Coder Import (b) (4) | 08 Sep 2020 17:20:58 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 08 Sep 2020 17:20:58 |
| | (b) (4) | |
| Data point term sent to Coder | System | 08 Sep 2020 17:19:26 |
| Datapoint queued for coding (5050282). | System | 08 Sep 2020 17:18:36 |
| User entered 'HYSTERECTOMY' | Adreanna Pou (b) (4) | 29 Aug 2020 14:30:09 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:05:52

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'UN UNK 1997' | Adreanna Pou (b) (4) | 29 Aug 2020 14:30:09 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:05:52

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 29 Aug 2020 14:30:09 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:05:52

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 29 Aug 2020 14:30:09 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:05:52

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 29 Aug 2020 14:30:09 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:05:52

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 29 Aug 2020 14:30:09 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:05:52

[Start Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered 'Jan 1997' | (b) (4), (b) (6) System | 29 Aug 2020 14:30:09 |

US3232056

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:05:52

[Start Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered '1997' | (b) (4), (b) (6) System | 29 Aug 2020 14:30:09 |

US3232056

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:05:52

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered empty. | (b) (4), (b) (6) System | 29 Aug 2020 14:30:09 |

US3232056

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:05:52

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered empty. | (b) (4), (b) (6) System | 29 Aug 2020 14:30:09 |

US3232056

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:05:52

Condition

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Water soluble vitamin deficiencies, PT: Vitamin B12 deficiency, LLT: Vitamin B12 deficiency - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Nov 2020 15:26:30 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Nov 2020 15:26:30 |
| | (b) (4) | |
| Data point term sent to Coder | System | 12 Nov 2020 15:25:54 |
| User entered 'vitamin b12 deficiency' | Adreanna Pou (b) (4) | 12 Nov 2020 15:25:21 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:05:52

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'un UNK 2018' | Adreanna Pou (b) (4) | 12 Nov 2020 15:25:21 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:05:52

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 12 Nov 2020 15:25:21 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:05:52

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 12 Nov 2020 15:25:21 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:05:52

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 12 Nov 2020 15:25:21 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:05:52

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 12 Nov 2020 15:25:21 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:05:52

[Start Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered 'Jan 2018' | (b) (4), (b) (6) System | 12 Nov 2020 15:25:21 |

US3232056

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:05:52

[Start Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered '2018' | (b) (4), (b) (6) System | 12 Nov 2020 15:25:21 |

US3232056

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:05:52

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered empty. | (b) (4), (b) (6) System | 12 Nov 2020 15:25:21 |

US3232056

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:05:52

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered empty. | (b) (4), (b) (6) System | 12 Nov 2020 15:25:21 |

US3232056

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:05:52

[Condition](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Nov 2020 15:33:34 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Nov 2020 15:33:34 |
| | (b) (4) | |
| Data point term sent to Coder | System | 12 Nov 2020 15:33:10 |
| User entered 'anemia' | Adreanna Pou (b) (4) | 12 Nov 2020 15:32:23 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:05:52

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'un UNK 1994' | Adreanna Pou (b) (4) | 12 Nov 2020 15:32:23 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:05:52

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 12 Nov 2020 15:32:23 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:05:52

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 12 Nov 2020 15:32:23 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:05:52

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 12 Nov 2020 15:32:23 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:05:52

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 12 Nov 2020 15:32:23 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:05:52

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered 'Jan 1994' | (b) (4), (b) (6) System | 12 Nov 2020 15:32:23 |

US3232056

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:05:52

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered '1994' | (b) (4), (b) (6) System | 12 Nov 2020 15:32:23 |

US3232056

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:05:52

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered empty. | (b) (4), (b) (6) System | 12 Nov 2020 15:32:23 |

US3232056

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:05:52

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered empty. | (b) (4), (b) (6) System | 12 Nov 2020 15:32:23 |

US3232056

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:37:30 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '17 Aug 2020' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:37:30 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '10:00' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:37:30 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered '17 Aug 2020 10:00' | (b) (4), (b) (6) System | 18 Aug 2020 12:37:30 |

US3232056

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Height (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '155' cm | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:37:30 |
| | (b) (4) | |
| DataPoint set to visible. | System | 17 Aug 2020 16:23:31 |

US3232056

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Weight (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '59.2' kg | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:37:30 |
| | (b) (4) | |
| DataPoint set to visible. | System | 17 Aug 2020 16:23:31 |

US3232056

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

BMI (xxx.x)

| Audit | User | Time (GMT) |
|--------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| Amendment Manager: User entered '24.64100' | (b) (4), (b) (6) | |
| User entered '24.6' | System | 16 Sep 2020 23:59:36 |
| DataPoint set to visible. | System | 18 Aug 2020 12:37:30 |
| | System | 17 Aug 2020 16:23:31 |

US3232056

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[BMI units](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User entered 'kg/m2' | System | 18 Aug 2020 12:37:30 |
| DataPoint set to visible. | System | 17 Aug 2020 16:23:31 |

US3232056

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '98.5' F | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:37:30 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Oral (Oral)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:37:30 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:37:30 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '71' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:37:30 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered 'bpm' | (b) (4), (b) (6) System | 18 Aug 2020 12:37:30 |

US3232056

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '18' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:37:30 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered 'breaths/min' | (b) (4), (b) (6) System | 18 Aug 2020 12:37:30 |

US3232056

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '125' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:37:30 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered 'mmHg' | (b) (4), (b) (6) System | 18 Aug 2020 12:37:30 |

US3232056

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '65' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:37:30 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User entered 'mmHg' | (b) (4), (b) (6) System | 18 Aug 2020 12:37:30 |

US3232056

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |

US3232056

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |

US3232056

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:52

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:37:43 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:52

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| Amendment Manager: Query closed during migration process because the edit check no longer exists in target version. | System | 30 Sep 2020 21:36:25 |
| User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System). | System | 14 Sep 2020 16:14:59 |
| User entered '17 Aug 2020' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:37:43 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:05:52

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '17 Aug 2020' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:39:07 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:05:52

[Is the participant of childbearing potential?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:39:07 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:05:52

If No, what is the reason?

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| User closed query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with this procedure in MH ecrf if applicable. Review and update as appropriate.' (Site from DM). | (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) | 01 Sep 2020 17:05:17 |
| Query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with this procedure in MH ecrf if applicable. Review and update as appropriate.' answered with 'HYSTERECTOMY ADDED' (Site from DM). | Adreanna Pou (b) (4) (b) (4) | 29 Aug 2020 14:28:34 |
| User opened query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with this procedure in MH ecrf if applicable. Review and update as appropriate.' (Site from DM). | (b) (4), (b) (6) (b) (4), (b) (6) | 27 Aug 2020 02:21:13 |
| User entered 'Surgically sterile (SURGICALLY STERILE)' | Jerrica Sullivan (b) (4) (b) (4) | 18 Aug 2020 12:39:07 |

US3232056

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:05:52

If Partner medically sterile or Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:39:07 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:05:52

If Surgically sterile, date of surgery (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'un UNK 1997' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:39:07 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:05:52

Date of surgery unknown

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:39:07 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:05:52

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:39:07 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:05:52

Date of last menstruation unknown

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:39:07 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:52

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:39:48 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:52

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:39:48 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:52

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) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:39:48 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:52

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) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:39:48 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:52

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:39:48 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:52

[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) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:39:48 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:52

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) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:39:48 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:52

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) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:39:48 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:52

[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) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:39:48 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:52

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) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:39:48 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:52

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) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:39:48 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:52

Other

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:39:48 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:52

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:39:48 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:52

No Risk Identified

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:39:48 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:52

[Resides in Nursing Home or Assisted Living Facility](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:39:48 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:52

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) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:39:48 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:52

[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) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:39:48 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:52

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) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:39:48 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:52

[Resides in a single family home](#) (i.e., detached housing)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:39:48 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:52

Other

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'I' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:39:48 |
| | (b) (4) | |

US3232056

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:52

[Specify](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:55:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Resident in a community with ongoing person to person transmission' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:39:48 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:05:52

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:40:02 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:05:52

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '17 Aug 2020' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:40:02 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:05:52

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Clinic (Clinic)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:40:02 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:05:52

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered 'VISIT1' | System | 18 Aug 2020 12:40:02 |

US3232056

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:52

What was the date of randomization? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '17 AUG 2020' | RWS_ENDPOINT | 17 Aug 2020 15:49:49 |
| | ENDPOINT (b) (4) | |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:52

What was the participant's randomization number?

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------|---------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 21 Aug 2020 04:58:13 |
| Amendment Manager: Data point set to conformant. | System | 21 Aug 2020 04:58:13 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 17 Aug 2020 15:49:49 |
| User entered '186438' (non-conformant). | RWS_ENDPOINT ENDPOINT (b) (4) (b) (4) | 17 Aug 2020 15:49:49 |

US3232056

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:52

[In what Cohort was the participant enrolled?](#)

| Audit | User | Time (GMT) |
|-------------------------------|-------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '>=65 years (3)' | RWS_ENDPOINT | 17 Aug 2020 15:49:49 |
| | ENDPOINT (b) (4) | |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:52

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:40:59 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:52

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:40:59 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:52

Severe obesity (body mass index > or = 40kg/m2

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:40:59 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:52

[Diabetes \(Type I, Type 2, or gestational\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:40:59 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:52

[Liver Disease](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:40:59 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:52

[Human Immunodeficiency Virus \(HIV\) infection](#)

| Audit | User | Time (GMT) |
|----------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 01 Dec 2020 19:26:28 |
| | (b) (4) | |
| Amendment Manager: DataPoint set to visible. | System | 19 Sep 2020 10:22:35 |
| Amendment Manager inserted this DataPoint. | System | 19 Sep 2020 07:37:06 |

US3232056

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:52

Height

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM). | (b) (4), (b) (6) | 01 Sep 2020 11:38:07 |
| | (b) (4), (b) (6) | |
| Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'correction' (Site from DM). | Adreanna Pou (b) (4) | 28 Aug 2020 17:17:20 |
| | (b) (4) | |
| User entered missing code ND - Not Done; reason for change Per Query Resolution | Adreanna Pou (b) (4) | 28 Aug 2020 17:17:12 |
| | (b) (4) | |
| User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM). | (b) (4), (b) (6) | 28 Aug 2020 15:23:06 |
| | (b) (4), (b) (6) | |
| User entered '155' cm | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:45:29 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:52

Weight

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM). | (b) (4), (b) (6) | 01 Sep 2020 11:38:09 |
| | (b) (4), (b) (6) | |
| Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'correction' (Site from DM). | Adreanna Pou (b) (4) | 28 Aug 2020 17:17:26 |
| | (b) (4) | |
| User entered missing code ND - Not Done; reason for change Per Query Resolution | Adreanna Pou (b) (4) | 28 Aug 2020 17:17:12 |
| | (b) (4) | |
| User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM). | (b) (4), (b) (6) | 28 Aug 2020 15:23:14 |
| | (b) (4), (b) (6) | |
| User entered '59.2' kg | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:45:29 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:52

Height

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM). | (b) (4), (b) (6) | 01 Sep 2020 11:38:07 |
| | (b) (4), (b) (6) | |
| Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'correction' (Site from DM). | Adreanna Pou (b) (4) | 28 Aug 2020 17:17:20 |
| | (b) (4) | |
| User entered missing code ND - Not Done; reason for change Per Query Resolution | Adreanna Pou (b) (4) | 28 Aug 2020 17:17:12 |
| | (b) (4) | |
| User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM). | (b) (4), (b) (6) | 28 Aug 2020 15:23:06 |
| | (b) (4), (b) (6) | |
| User entered '155' cm | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:45:29 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:52

Weight

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM). | (b) (4), (b) (6) | 01 Sep 2020 11:38:09 |
| | (b) (4), (b) (6) | |
| Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'correction' (Site from DM). | Adreanna Pou (b) (4) | 28 Aug 2020 17:17:26 |
| | (b) (4) | |
| User entered missing code ND - Not Done; reason for change Per Query Resolution | Adreanna Pou (b) (4) | 28 Aug 2020 17:17:12 |
| | (b) (4) | |
| User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM). | (b) (4), (b) (6) | 28 Aug 2020 15:23:14 |
| | (b) (4), (b) (6) | |
| User entered '59.2' kg | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:45:29 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

[Timepoint](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User accepted default value 'Pre-Dose (PREDOSE)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:45:29 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:45:29 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '17 Aug 2020' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:45:29 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '10:00' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:45:29 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered '17 Aug 2020 10:00' | (b) (4), (b) (6) | 18 Aug 2020 12:45:29 |
| | System | |

US3232056

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '98.5' F | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:45:29 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Oral (Oral)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:45:29 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:45:29 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '71' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:45:29 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered 'bpm' | System | 18 Aug 2020 12:45:29 |

US3232056

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '18' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:45:29 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered 'breaths/min' | System | 18 Aug 2020 12:45:29 |

US3232056

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '125' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:45:29 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered 'mmHg' | (b) (4), (b) (6) System | 18 Aug 2020 12:45:29 |

US3232056

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '65' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:45:29 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered 'mmHg' | (b) (4), (b) (6) System | 18 Aug 2020 12:45:29 |

US3232056

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:52

Height

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM). | (b) (4), (b) (6) | 01 Sep 2020 11:38:07 |
| | (b) (4), (b) (6) | |
| Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'correction' (Site from DM). | Adreanna Pou (b) (4) | 28 Aug 2020 17:17:20 |
| | (b) (4) | |
| User entered missing code ND - Not Done; reason for change Per Query Resolution | Adreanna Pou (b) (4) | 28 Aug 2020 17:17:12 |
| | (b) (4) | |
| User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM). | (b) (4), (b) (6) | 28 Aug 2020 15:23:06 |
| | (b) (4), (b) (6) | |
| User entered '155' cm | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:45:29 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:52

Weight

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM). | (b) (4), (b) (6) | 01 Sep 2020 11:38:09 |
| | (b) (4), (b) (6) | |
| Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'correction' (Site from DM). | Adreanna Pou (b) (4) | 28 Aug 2020 17:17:26 |
| | (b) (4) | |
| User entered missing code ND - Not Done; reason for change Per Query Resolution | Adreanna Pou (b) (4) | 28 Aug 2020 17:17:12 |
| | (b) (4) | |
| User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM). | (b) (4), (b) (6) | 28 Aug 2020 15:23:14 |
| | (b) (4), (b) (6) | |
| User entered '59.2' kg | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:45:29 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

[Timepoint](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User accepted default value 'Post-Dose (POSTDOSE)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:45:29 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:45:29 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '17 Aug 2020' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:45:29 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version. | | 21 Aug 2020 04:58:10 |
| 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). | | 18 Aug 2020 12:45:29 |
| User entered '11:45' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:45:29 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered '17 Aug 2020 11:45' | (b) (4), (b) (6) | 18 Aug 2020 12:45:29 |
| | System | |

US3232056

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | (b) (4), (b) (6) | 13 Oct 2020 10:59:35 |
| Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs' (Site from System). | Adreanna Pou (b) (4) | 12 Oct 2020 13:47:25 |
| | (b) (4) | |
| Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | System | 16 Sep 2020 23:59:36 |
| User entered '96.3' F | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:45:29 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

[Route of measurement](#)

| Audit | User | Time (GMT) |
|------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Other (Other)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:45:29 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'temporal' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:45:29 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '69' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:45:29 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered 'bpm' | System | 18 Aug 2020 12:45:29 |

US3232056

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '18' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:45:29 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered 'breaths/min' | (b) (4), (b) (6) | 18 Aug 2020 12:45:29 |
| | System | |

US3232056

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '116' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:45:29 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered 'mmHg' | (b) (4), (b) (6) System | 18 Aug 2020 12:45:29 |

US3232056

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '62' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:45:29 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered 'mmHg' | (b) (4), (b) (6) System | 18 Aug 2020 12:45:29 |

US3232056

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:52

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:42:50 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:52

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '17 Aug 2020' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:42:50 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:52

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 17 Aug 2020 16:23:58 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:52

If No, reason not given

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 17 Aug 2020 16:23:58 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:52

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 17 Aug 2020 16:23:58 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:52

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered 'MRNA-1273 OR PLACEBO' | (b) (4), (b) (6) | 17 Aug 2020 16:23:58 |
| | System | |

US3232056

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:52

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '17 Aug 2020' | Jerrica Sullivan (b) (4) | 17 Aug 2020 16:23:58 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:52

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '11:13' | Jerrica Sullivan (b) (4) | 17 Aug 2020 16:23:58 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:52

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered '17 Aug 2020 11:13' | (b) (4), (b) (6) | |
| | System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:52

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Left Arm (LEFT ARM)' | Jerrica Sullivan (b) (4) | 17 Aug 2020 16:23:58 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:52

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered 'ONCE' | System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:52

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered 'INTRAMUSCULAR' | (b) (4), (b) (6) | 17 Aug 2020 16:23:58 |
| | System | |

US3232056

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:52

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:42:39 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:52

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '17 Aug 2020' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:42:39 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:52

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '10:54' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:42:39 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:52

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered '17 Aug 2020 10:54' | (b) (4), (b) (6) | 18 Aug 2020 12:42:39 |
| | System | |

US3232056

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:05:52

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '17 Aug 2020' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:52:14 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:52

[Lab Test](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:52:14 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:52

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:52:14 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:52

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '10:55' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:52:14 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:52

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered '17 Aug 2020 10:55' | (b) (4), (b) (6) | |
| | System | 18 Aug 2020 12:52:14 |

US3232056

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:52

[Lab Test](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:52:14 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:52

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:52:14 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:52

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:52:14 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:52

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered empty. | (b) (4), (b) (6) | 18 Aug 2020 12:52:14 |
| | System | |

US3232056

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:05:52

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:43:21 |
| | (b) (4) | |

US3232056

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:05:52

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered 'I' | System | 18 Aug 2020 12:43:21 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 17 Aug 2020 16:23:58 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-17T11:34:04', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '66eb5db4-d7d8-4cee-ad16-95df52526ede' User entered 'Yes (Y)' | (b) (4), (b) (6) System | 17 Aug 2020 16:34:49 |
| | System | 17 Aug 2020 16:34:49 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-17T11:34:16', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '66eb5db4-d7d8-4cee-ad16-95df52526ede' User entered '96.3' | (b) (4), (b) (6) System | 17 Aug 2020 16:34:49 |
| | System | 17 Aug 2020 16:34:49 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-17T11:34:26', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '66eb5db4-d7d8-4cee-ad16-95df52526ede' User entered 'No (N)' | (b) (4), (b) (6) System | 17 Aug 2020 16:34:49 |
| | System | 17 Aug 2020 16:34:49 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-17T11:34:45', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '66eb5db4-d7d8-4cee-ad16-95df52526ede' User entered '17 Aug 2020 11:34' | (b) (4), (b) (6) System | 17 Aug 2020 16:34:49 |
| | System | 17 Aug 2020 16:34:49 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '17 Aug 2020 11:33' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '17 Aug 2020 14:03' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|---------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 17 Aug 2020 16:23:58 |
| User entered 'Day 1, after vaccination (at home)' | System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-17T21:05:37', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '6c75df10-1fca-4f71-b638-9aee0ea20fec' | (b) (4), (b) (6) | |
| User entered 'Yes (Y)' | System | 18 Aug 2020 02:06:16 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-17T21:05:52', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '6c75df10-1fca-4f71-b638-9ace0ea20fec' User entered '98.1' | (b) (4), (b) (6) System | 18 Aug 2020 02:06:16 |
| | System | 18 Aug 2020 02:06:16 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-17T21:05:57', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '6c75df10-1fca-4f71-b638-9aee0ea20fec' | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 18 Aug 2020 02:06:16 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-17T21:06:12', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '6c75df10-1fca-4f71-b638-9aee0ea20fec' User entered '17 Aug 2020 21:06' | (b) (4), (b) (6) System | 18 Aug 2020 02:06:16 |
| | System | 18 Aug 2020 02:06:16 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '17 Aug 2020 14:58' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '18 Aug 2020 11:59' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 17 Aug 2020 16:23:58 |
| User entered 'Day 2' | System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:52

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-18T21:09:00', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '0d9ce2ef-38d5-46da-bc01-0f70c364329c' User entered 'Yes (Y)' | (b) (4), (b) (6) System | 19 Aug 2020 02:09:28 |
| | System | 19 Aug 2020 02:09:28 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:52

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-18T21:09:11', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '0d9ce2ef-38d5-46da-bc01-0f70c364329c' User entered '98.2' | (b) (4), (b) (6) System | 19 Aug 2020 02:09:28 |
| | System | 19 Aug 2020 02:09:28 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:52

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-18T21:09:17', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '0d9ce2ef-38d5-46da-bc01-0f70c364329c' User entered 'No (N)' | (b) (4), (b) (6) System | 19 Aug 2020 02:09:28 |
| | System | 19 Aug 2020 02:09:28 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:52

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-18T21:09:25', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '0d9ce2ef-38d5-46da-bc01-0f70c364329c' User entered '18 Aug 2020 21:09' | (b) (4), (b) (6) System | 19 Aug 2020 02:09:28 |
| | System | 19 Aug 2020 02:09:28 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '18 Aug 2020 12:00' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '19 Aug 2020 11:59' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 17 Aug 2020 16:23:58 |
| User entered 'Day 3' | System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:52

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-19T21:01:22', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '97eb88c2-921c-4209-baa1-89e78e989e3a' User entered 'Yes (Y)' | (b) (4), (b) (6) System | 20 Aug 2020 02:01:45 |
| | System | 20 Aug 2020 02:01:45 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:52

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-19T21:01:29', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '97eb88c2-921c-4209-baa1-89e78e989e3a' User entered '98.2' | (b) (4), (b) (6) System | 20 Aug 2020 02:01:45 |
| | System | 20 Aug 2020 02:01:45 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:52

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-19T21:01:37', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '97eb88c2-921c-4209-baa1-89e78e989e3a' User entered 'No (N)' | (b) (4), (b) (6) System | 20 Aug 2020 02:01:45 |
| | System | 20 Aug 2020 02:01:45 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:52

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-19T21:01:43', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '97eb88c2-921c-4209-baa1-89e78e989e3a' User entered '19 Aug 2020 21:01' | (b) (4), (b) (6) System | 20 Aug 2020 02:01:45 |
| | System | 20 Aug 2020 02:01:45 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '19 Aug 2020 12:00' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '20 Aug 2020 11:59' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 17 Aug 2020 16:23:58 |
| User entered 'Day 4' | System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:52

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-20T21:32:59', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'cc7979da-32a6-4608-957e-eedc10018b23' User entered 'Yes (Y)' | (b) (4), (b) (6) System | 21 Aug 2020 02:33:23 |
| | System | 21 Aug 2020 02:33:23 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:52

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-20T21:33:06', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'cc7979da-32a6-4608-957e-eedc10018b23' User entered '98.0' | (b) (4), (b) (6) System | 21 Aug 2020 02:33:23 |
| | System | 21 Aug 2020 02:33:23 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:52

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-20T21:33:14', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'cc7979da-32a6-4608-957e-eedc10018b23' User entered 'No (N)' | (b) (4), (b) (6) System | 21 Aug 2020 02:33:23 |
| | System | 21 Aug 2020 02:33:23 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:52

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-20T21:33:21', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'cc7979da-32a6-4608-957e-eedc10018b23' User entered '20 Aug 2020 21:33' | (b) (4), (b) (6) System | 21 Aug 2020 02:33:23 |
| | System | 21 Aug 2020 02:33:23 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '20 Aug 2020 12:00' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '21 Aug 2020 11:59' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 17 Aug 2020 16:23:58 |
| User entered 'Day 5' | System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:52

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-21T20:57:35', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'af312b7a-f444-492d-869f-9f9d3135d71b' User entered 'Yes (Y)' | (b) (4), (b) (6) System | 22 Aug 2020 01:57:59 |
| | System | 22 Aug 2020 01:57:59 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:52

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-21T20:57:42', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'af312b7a-f444-492d-869f-9f9d3135d71b' User entered '98.1' | (b) (4), (b) (6) System | 22 Aug 2020 01:57:59 |
| | System | 22 Aug 2020 01:57:59 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:52

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-21T20:57:48', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'af312b7a-f444-492d-869f-9f9d3135d71b' | (b) (4), (b) (6) | |
| | System | 22 Aug 2020 01:57:59 |
| User entered 'No (N)' | System | 22 Aug 2020 01:57:59 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:52

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-21T20:57:57', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'af312b7a-f444-492d-869f-9f9d3135d71b' User entered '21 Aug 2020 20:57' | (b) (4), (b) (6) System | 22 Aug 2020 01:57:59 |
| | System | 22 Aug 2020 01:57:59 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '21 Aug 2020 12:00' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '22 Aug 2020 11:59' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 17 Aug 2020 16:23:58 |
| User entered 'Day 6' | System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:52

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-22T21:43:27', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '1dd878f8-f1bd-4aae-afc7-4aa966ee4662' | (b) (4), (b) (6) | |
| | System | 23 Aug 2020 02:44:09 |
| User entered 'Yes (Y)' | System | 23 Aug 2020 02:44:09 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:52

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-22T21:43:36', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '1dd878f8-f1bd-4aae-afc7-4aa966ee4662' User entered '98.4' | (b) (4), (b) (6) System | 23 Aug 2020 02:44:09 |
| | System | 23 Aug 2020 02:44:09 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:52

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-22T21:43:52', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '1dd878f8-f1bd-4aae-afc7-4aa966ee4662' | (b) (4), (b) (6) | |
| | System | 23 Aug 2020 02:44:09 |
| User entered 'No (N)' | System | 23 Aug 2020 02:44:09 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:52

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-22T21:44:05', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '1dd878f8-f1bd-4aae-afc7-4aa966ee4662' | (b) (4), (b) (6) System | 23 Aug 2020 02:44:09 |
| User entered '22 Aug 2020 21:44' | System | 23 Aug 2020 02:44:09 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '22 Aug 2020 12:00' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '23 Aug 2020 11:59' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 17 Aug 2020 16:23:58 |
| User entered 'Day 7' | System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:52

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-23T21:41:00', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '411ea84e-228a-40cc-ade5-20ce9e04b756' | (b) (4), (b) (6) | |
| System | | 24 Aug 2020 02:41:28 |
| User entered 'Yes (Y)' | System | 24 Aug 2020 02:41:28 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:52

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-23T21:41:07', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '411ea84e-228a-40cc-ade5-20ce9e04b756' User entered '98.3' | (b) (4), (b) (6) System | 24 Aug 2020 02:41:28 |
| | System | 24 Aug 2020 02:41:28 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:52

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-23T21:41:13', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '411ea84e-228a-40cc-ade5-20ce9e04b756' | (b) (4), (b) (6) | |
| System | | 24 Aug 2020 02:41:28 |
| User entered 'No (N)' | System | 24 Aug 2020 02:41:28 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:52

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-23T21:41:23', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '411ea84e-228a-40cc-ade5-20ce9e04b756' User entered '23 Aug 2020 21:41' | (b) (4), (b) (6) System | 24 Aug 2020 02:41:28 |
| | System | 24 Aug 2020 02:41:28 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '23 Aug 2020 12:00' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '24 Aug 2020 11:59' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| Data entry locked. | (b) (4), (b) (6) | |
| | System | 17 Aug 2020 16:23:58 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-17T11:35:08', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'd732a12e-8055-4c30-87b4-e871b906f759' User entered 'None (1)' | (b) (4), (b) (6) System | 17 Aug 2020 16:35:51 |
| | System | 17 Aug 2020 16:35:51 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-17T11:35:23', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'd732a12e-8055-4c30-87b4-e871b906f759' | (b) (4), (b) (6) System | 17 Aug 2020 16:35:51 |
| User entered 'No (N)' | System | 17 Aug 2020 16:35:51 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-17T11:35:29', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'd732a12e-8055-4c30-87b4-e871b906f759' | (b) (4), (b) (6) System | 17 Aug 2020 16:35:51 |
| User entered 'No (N)' | System | 17 Aug 2020 16:35:51 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-17T11:35:40', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'd732a12e-8055-4c30-87b4-e871b906f759' User entered 'None (1)' | (b) (4), (b) (6) System | 17 Aug 2020 16:35:51 |
| | System | 17 Aug 2020 16:35:51 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-17T11:35:48', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'd732a12e-8055-4c30-87b4-e871b906f759' | (b) (4), (b) (6) System | 17 Aug 2020 16:35:51 |
| User entered '17 Aug 2020 11:35' | System | 17 Aug 2020 16:35:51 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| User entered '17 Aug 2020 11:33' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| User entered '17 Aug 2020 14:03' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|---------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 17 Aug 2020 16:23:58 |
| User entered 'Day 1, after vaccination (at home)' | System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-17T21:06:22', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '31d5bd01-5c4f-46fa-a4b5-f9f6fa5cc2db' User entered 'None (1)' | (b) (4), (b) (6) System | 18 Aug 2020 02:07:00 |
| | System | 18 Aug 2020 02:07:00 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

Is there any **REDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-17T21:06:34', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '31d5bd01-5c4f-46fa-a4b5-f9f6fa5cc2db' User entered 'No (N)' | (b) (4), (b) (6) System | 18 Aug 2020 02:07:00 |
| | System | 18 Aug 2020 02:07:00 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-17T21:06:39', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '31d5bd01-5c4f-46fa-a4b5-f9f6fa5cc2db' User entered 'No (N)' | (b) (4), (b) (6) System | 18 Aug 2020 02:07:00 |
| | System | 18 Aug 2020 02:07:00 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-17T21:06:47', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '31d5bd01-5c4f-46fa-a4b5-f9f6fa5cc2db' User entered 'None (1)' | (b) (4), (b) (6) System | 18 Aug 2020 02:07:00 |
| | System | 18 Aug 2020 02:07:00 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-17T21:06:58', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '31d5bd01-5c4f-46fa-a4b5-f9f6fa5cc2db' User entered '17 Aug 2020 21:06' | (b) (4), (b) (6) System | 18 Aug 2020 02:07:00 |
| | System | 18 Aug 2020 02:07:00 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| User entered '17 Aug 2020 14:58' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| User entered '18 Aug 2020 11:59' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 17 Aug 2020 16:23:58 |
| User entered 'Day 2' | System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:52

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-18T21:09:41', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'b0cc9d86-a54d-4403-ab1c-8f3f7c2683a9' User entered 'None (1)' | (b) (4), (b) (6) System | 19 Aug 2020 02:10:20 |
| | System | 19 Aug 2020 02:10:20 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:52

Is there any **REDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-18T21:09:49', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'b0cc9d86-a54d-4403-ab1c-8f3f7c2683a9' User entered 'No (N)' | (b) (4), (b) (6) System | 19 Aug 2020 02:10:20 |
| | System | 19 Aug 2020 02:10:20 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-18T21:09:56', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'b0cc9d86-a54d-4403-ab1c-8f3f7c2683a9' User entered 'No (N)' | (b) (4), (b) (6) System | 19 Aug 2020 02:10:20 |
| | System | 19 Aug 2020 02:10:20 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:52

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-18T21:10:04', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'b0cc9d86-a54d-4403-ab1c-8f3f7c2683a9' User entered 'None (1)' | (b) (4), (b) (6) System | 19 Aug 2020 02:10:20 |
| | System | 19 Aug 2020 02:10:20 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:52

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-18T21:10:18', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'b0cc9d86-a54d-4403-ab1c-8f3f7c2683a9' User entered '18 Aug 2020 21:10' | (b) (4), (b) (6) System | 19 Aug 2020 02:10:20 |
| | System | 19 Aug 2020 02:10:20 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| User entered '18 Aug 2020 12:00' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| User entered '19 Aug 2020 11:59' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 17 Aug 2020 16:23:58 |
| User entered 'Day 3' | System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:52

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-19T21:01:52', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'dd3f9419-2df1-4827-b4d4-6d2ade462dec' User entered 'None (1)' | (b) (4), (b) (6) System | 20 Aug 2020 02:02:23 |
| | System | 20 Aug 2020 02:02:23 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:52

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-19T21:02:01', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'dd3f9419-2df1-4827-b4d4-6d2ade462dec' User entered 'No (N)' | (b) (4), (b) (6) System | 20 Aug 2020 02:02:23 |
| | System | 20 Aug 2020 02:02:23 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-19T21:02:04', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'dd3f9419-2df1-4827-b4d4-6d2ade462dec' User entered 'No (N)' | (b) (4), (b) (6) System | 20 Aug 2020 02:02:23 |
| | System | 20 Aug 2020 02:02:23 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:52

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-19T21:02:11', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'dd3f9419-2df1-4827-b4d4-6d2ade462dec' | (b) (4), (b) (6) System | 20 Aug 2020 02:02:23 |
| User entered 'None (1)' | System | 20 Aug 2020 02:02:23 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:52

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-19T21:02:18', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'dd3f9419-2df1-4827-b4d4-6d2ade462dec' | (b) (4), (b) (6) System | 20 Aug 2020 02:02:23 |
| User entered '19 Aug 2020 21:02' | System | 20 Aug 2020 02:02:23 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| User entered '19 Aug 2020 12:00' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| User entered '20 Aug 2020 11:59' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 17 Aug 2020 16:23:58 |
| User entered 'Day 4' | System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:52

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-20T21:33:35', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'cec26e43-5742-4ec3-b5d1-8a7f3a38e49b' User entered 'None (1)' | (b) (4), (b) (6) System | 21 Aug 2020 02:34:01 |
| | System | 21 Aug 2020 02:34:01 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:52

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-20T21:33:39', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'cec26e43-5742-4ec3-b5d1-8a7f3a38e49b' User entered 'No (N)' | (b) (4), (b) (6) System | 21 Aug 2020 02:34:01 |
| | System | 21 Aug 2020 02:34:01 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-20T21:33:45', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'cec26e43-5742-4ec3-b5d1-8a7f3a38e49b' User entered 'No (N)' | (b) (4), (b) (6) System | 21 Aug 2020 02:34:01 |
| | System | 21 Aug 2020 02:34:01 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:52

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-20T21:33:49', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'cec26e43-5742-4ec3-b5d1-8a7f3a38e49b' User entered 'None (1)' | (b) (4), (b) (6) System | 21 Aug 2020 02:34:01 |
| | System | 21 Aug 2020 02:34:01 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:52

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-20T21:33:57', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'cec26e43-5742-4ec3-b5d1-8a7f3a38e49b' User entered '20 Aug 2020 21:33' | (b) (4), (b) (6) System | 21 Aug 2020 02:34:01 |
| | System | 21 Aug 2020 02:34:01 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| User entered '20 Aug 2020 12:00' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| User entered '21 Aug 2020 11:59' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 17 Aug 2020 16:23:58 |
| User entered 'Day 5' | System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:52

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-21T20:58:06', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '41067bd6-6d02-4300-b640-eb2f26129e10' User entered 'None (1)' | (b) (4), (b) (6) System | 22 Aug 2020 01:58:34 |
| | System | 22 Aug 2020 01:58:34 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:52

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-21T20:58:10', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '41067bd6-6d02-4300-b640-eb2f26129e10' User entered 'No (N)' | (b) (4), (b) (6) System | 22 Aug 2020 01:58:34 |
| | System | 22 Aug 2020 01:58:34 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-21T20:58:13', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '41067bd6-6d02-4300-b640-eb2f26129e10' User entered 'No (N)' | (b) (4), (b) (6) System | 22 Aug 2020 01:58:34 |
| | System | 22 Aug 2020 01:58:34 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:52

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-21T20:58:18', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '41067bd6-6d02-4300-b640-eb2f26129e10' | (b) (4), (b) (6) System | 22 Aug 2020 01:58:34 |
| User entered 'None (1)' | System | 22 Aug 2020 01:58:34 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:52

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-21T20:58:30', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '41067bd6-6d02-4300-b640-eb2f26129e10' User entered '21 Aug 2020 20:58' | (b) (4), (b) (6) System | 22 Aug 2020 01:58:34 |
| | System | 22 Aug 2020 01:58:34 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| User entered '21 Aug 2020 12:00' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| User entered '22 Aug 2020 11:59' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 17 Aug 2020 16:23:58 |
| User entered 'Day 6' | System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:52

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-22T21:44:18', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '74ba944d-cb06-4717-9e3b-ffc9858301c4' User entered 'None (1)' | (b) (4), (b) (6) System | 23 Aug 2020 02:44:42 |
| | System | 23 Aug 2020 02:44:42 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:52

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-22T21:44:21', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '74ba944d-cb06-4717-9e3b-ffc9858301c4' User entered 'No (N)' | (b) (4), (b) (6) System | 23 Aug 2020 02:44:42 |
| | System | 23 Aug 2020 02:44:42 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-22T21:44:25', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '74ba944d-cb06-4717-9e3b-ffc9858301c4' User entered 'No (N)' | (b) (4), (b) (6) System | 23 Aug 2020 02:44:42 |
| | System | 23 Aug 2020 02:44:42 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:52

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-22T21:44:29', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '74ba944d-cb06-4717-9e3b-ffc9858301c4' User entered 'None (1)' | (b) (4), (b) (6) System | 23 Aug 2020 02:44:42 |
| | System | 23 Aug 2020 02:44:42 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:52

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-22T21:44:41', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '74ba944d-cb06-4717-9e3b-ffc9858301c4' User entered '22 Aug 2020 21:44' | (b) (4), (b) (6) System | 23 Aug 2020 02:44:42 |
| | System | 23 Aug 2020 02:44:42 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| User entered '22 Aug 2020 12:00' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| User entered '23 Aug 2020 11:59' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 17 Aug 2020 16:23:58 |
| User entered 'Day 7' | System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:52

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-23T21:41:30', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '50de3e74-c1e5-429e-90c2-7290e457a20e' User entered 'None (1)' | (b) (4), (b) (6) System | 24 Aug 2020 02:41:56 |
| | System | 24 Aug 2020 02:41:56 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:52

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-23T21:41:34', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '50de3e74-c1e5-429e-90c2-7290e457a20e' User entered 'No (N)' | (b) (4), (b) (6) System | 24 Aug 2020 02:41:56 |
| | System | 24 Aug 2020 02:41:56 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-23T21:41:40', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '50de3e74-c1e5-429e-90c2-7290e457a20e' User entered 'No (N)' | (b) (4), (b) (6) System | 24 Aug 2020 02:41:56 |
| | System | 24 Aug 2020 02:41:56 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:52

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-23T21:41:45', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '50de3e74-c1e5-429e-90c2-7290e457a20e' User entered 'None (1)' | (b) (4), (b) (6) System | 24 Aug 2020 02:41:56 |
| | System | 24 Aug 2020 02:41:56 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:52

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-23T21:41:53', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '50de3e74-c1e5-429e-90c2-7290e457a20e' User entered '23 Aug 2020 21:41' | (b) (4), (b) (6) System | 24 Aug 2020 02:41:56 |
| | System | 24 Aug 2020 02:41:56 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| User entered '23 Aug 2020 12:00' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| User entered '24 Aug 2020 11:59' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| Data entry locked. | (b) (4), (b) (6) | |
| | System | 17 Aug 2020 16:23:58 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

HEADACHE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-17T11:36:00', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '37b60a3f-4549-45de-9175-eb8a23be41ba' User entered 'None (0)' | (b) (4), (b) (6) System | 17 Aug 2020 16:36:58 |
| | System | 17 Aug 2020 16:36:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

FATIGUE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-17T11:36:08', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '37b60a3f-4549-45de-9175-eb8a23be41ba' User entered 'None (0)' | (b) (4), (b) (6) System | 17 Aug 2020 16:36:58 |
| | System | 17 Aug 2020 16:36:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-17T11:36:15', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '37b60a3f-4549-45de-9175-eb8a23be41ba' User entered 'None (0)' | (b) (4), (b) (6) System | 17 Aug 2020 16:36:58 |
| | System | 17 Aug 2020 16:36:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-17T11:36:20', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '37b60a3f-4549-45de-9175-eb8a23be41ba' User entered 'None (0)' | (b) (4), (b) (6) System | 17 Aug 2020 16:36:58 |
| | System | 17 Aug 2020 16:36:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-17T11:36:26', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '37b60a3f-4549-45de-9175-eb8a23be41ba' User entered 'None (0)' | (b) (4), (b) (6) System | 17 Aug 2020 16:36:58 |
| | System | 17 Aug 2020 16:36:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

CHILLS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-17T11:36:29', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '37b60a3f-4549-45de-9175-eb8a23be41ba' User entered 'None (0)' | (b) (4), (b) (6) System | 17 Aug 2020 16:36:58 |
| | System | 17 Aug 2020 16:36:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

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) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-17T11:36:43', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '37b60a3f-4549-45de-9175-eb8a23be41ba' User entered 'No (N)' | (b) (4), (b) (6) System | 17 Aug 2020 16:36:58 |
| | System | 17 Aug 2020 16:36:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-17T11:36:56', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '37b60a3f-4549-45de-9175-eb8a23be41ba' User entered '17 Aug 2020 11:36' | (b) (4), (b) (6) System | 17 Aug 2020 16:36:58 |
| | System | 17 Aug 2020 16:36:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| User entered '17 Aug 2020 11:33' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| User entered '17 Aug 2020 14:03' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|---------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 17 Aug 2020 16:23:58 |
| User entered 'Day 1, after vaccination (at home)' | System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

HEADACHE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-17T21:07:09', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '8dbbe276-2a6d-4a44-9184-806bec38893d' User entered 'None (0)' | (b) (4), (b) (6) System | 18 Aug 2020 02:08:05 |
| | System | 18 Aug 2020 02:08:05 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

FATIGUE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-17T21:07:18', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '8dbbe276-2a6d-4a44-9184-806bec38893d' User entered 'None (0)' | (b) (4), (b) (6) System | 18 Aug 2020 02:08:05 |
| | System | 18 Aug 2020 02:08:05 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-17T21:07:23', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '8dbbe276-2a6d-4a44-9184-806bec38893d' User entered 'None (0)' | (b) (4), (b) (6) System | 18 Aug 2020 02:08:05 |
| | System | 18 Aug 2020 02:08:05 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-17T21:07:27', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '8dbbe276-2a6d-4a44-9184-806bec38893d' User entered 'None (0)' | (b) (4), (b) (6) System | 18 Aug 2020 02:08:05 |
| | System | 18 Aug 2020 02:08:05 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-17T21:07:31', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '8dbbe276-2a6d-4a44-9184-806bec38893d' User entered 'None (0)' | (b) (4), (b) (6) System | 18 Aug 2020 02:08:05 |
| | System | 18 Aug 2020 02:08:05 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

CHILLS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-17T21:07:35', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '8dbbe276-2a6d-4a44-9184-806bec38893d' User entered 'None (0)' | (b) (4), (b) (6) System | 18 Aug 2020 02:08:05 |
| | System | 18 Aug 2020 02:08:05 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

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) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-17T21:07:47', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '8dbbe276-2a6d-4a44-9184-806bec38893d' User entered 'No (N)' | (b) (4), (b) (6) System | 18 Aug 2020 02:08:05 |
| | System | 18 Aug 2020 02:08:05 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-17T21:08:01', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '8dbbe276-2a6d-4a44-9184-806bec38893d' User entered '17 Aug 2020 21:08' | (b) (4), (b) (6) System | 18 Aug 2020 02:08:05 |
| | System | 18 Aug 2020 02:08:05 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| User entered '17 Aug 2020 14:58' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| User entered '18 Aug 2020 11:59' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 17 Aug 2020 16:23:58 |
| User entered 'Day 2' | System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:52

HEADACHE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-18T21:10:28', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '9eae804e-903c-4325-9b50-e1f5c1a6caf0' User entered 'None (0)' | (b) (4), (b) (6) System | 19 Aug 2020 02:11:22 |
| | System | 19 Aug 2020 02:11:22 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:52

FATIGUE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-18T21:10:35', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '9eae804e-903c-4325-9b50-e1f5c1a6caf0' User entered 'None (0)' | (b) (4), (b) (6) System | 19 Aug 2020 02:11:22 |
| | System | 19 Aug 2020 02:11:22 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:52

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-18T21:10:40', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '9eae804e-903c-4325-9b50-e1f5c1a6caf0' User entered 'None (0)' | (b) (4), (b) (6) System | 19 Aug 2020 02:11:22 |
| | System | 19 Aug 2020 02:11:22 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:52

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-18T21:10:44', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '9eae804e-903c-4325-9b50-e1f5c1a6caf0' User entered 'None (0)' | (b) (4), (b) (6) System | 19 Aug 2020 02:11:22 |
| | System | 19 Aug 2020 02:11:22 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:52

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-18T21:10:48', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '9eae804e-903c-4325-9b50-e1f5c1a6caf0' User entered 'None (0)' | (b) (4), (b) (6) System | 19 Aug 2020 02:11:22 |
| | System | 19 Aug 2020 02:11:22 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:52

CHILLS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-18T21:10:52', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '9eae804e-903c-4325-9b50-e1f5c1a6caf0' User entered 'None (0)' | (b) (4), (b) (6) System | 19 Aug 2020 02:11:22 |
| | System | 19 Aug 2020 02:11:22 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:52

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) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-18T21:11:03', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '9eae804e-903c-4325-9b50-e1f5c1a6caf0' User entered 'No (N)' | (b) (4), (b) (6) System | 19 Aug 2020 02:11:22 |
| | System | 19 Aug 2020 02:11:22 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:52

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-18T21:11:21', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '9eae804e-903c-4325-9b50-e1f5c1a6caf0' User entered '18 Aug 2020 21:11' | (b) (4), (b) (6) System | 19 Aug 2020 02:11:22 |
| | System | 19 Aug 2020 02:11:22 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| User entered '18 Aug 2020 12:00' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| User entered '19 Aug 2020 11:59' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 17 Aug 2020 16:23:58 |
| User entered 'Day 3' | System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:52

HEADACHE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-19T21:02:29', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '8ceb56eb-7481-4955-8ae0-dd4402bf6536' User entered 'None (0)' | (b) (4), (b) (6) System | 20 Aug 2020 02:03:07 |
| | System | 20 Aug 2020 02:03:07 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:52

FATIGUE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-19T21:02:33', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '8ceb56eb-7481-4955-8ae0-dd4402bf6536' User entered 'None (0)' | (b) (4), (b) (6) System | 20 Aug 2020 02:03:07 |
| | System | 20 Aug 2020 02:03:07 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:52

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-19T21:02:37', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '8ceb56eb-7481-4955-8ae0-dd4402bf6536' User entered 'None (0)' | (b) (4), (b) (6) System | 20 Aug 2020 02:03:07 |
| | System | 20 Aug 2020 02:03:07 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:52

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-19T21:02:41', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '8ceb56eb-7481-4955-8ae0-dd4402bf6536' User entered 'None (0)' | (b) (4), (b) (6) System | 20 Aug 2020 02:03:07 |
| | System | 20 Aug 2020 02:03:07 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:52

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-19T21:02:44', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '8ceb56eb-7481-4955-8ae0-dd4402bf6536' User entered 'None (0)' | (b) (4), (b) (6) System | 20 Aug 2020 02:03:07 |
| | System | 20 Aug 2020 02:03:07 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:52

CHILLS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-19T21:02:48', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '8ceb56eb-7481-4955-8ae0-dd4402bf6536' User entered 'None (0)' | (b) (4), (b) (6) System | 20 Aug 2020 02:03:07 |
| | System | 20 Aug 2020 02:03:07 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:52

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) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-19T21:02:54', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '8ceb56eb-7481-4955-8ae0-dd4402bf6536' User entered 'No (N)' | (b) (4), (b) (6) System | 20 Aug 2020 02:03:07 |
| | System | 20 Aug 2020 02:03:07 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:52

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-19T21:03:05', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '8ceb56eb-7481-4955-8ae0-dd4402bf6536' User entered '19 Aug 2020 21:03' | (b) (4), (b) (6) System | 20 Aug 2020 02:03:07 |
| | System | 20 Aug 2020 02:03:07 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| User entered '19 Aug 2020 12:00' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| User entered '20 Aug 2020 11:59' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 17 Aug 2020 16:23:58 |
| User entered 'Day 4' | System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:52

HEADACHE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-20T21:34:06', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'f705bb24-b9cc-4d46-af89-57a41f8949ff' User entered 'None (0)' | (b) (4), (b) (6) System | 21 Aug 2020 02:34:49 |
| | System | 21 Aug 2020 02:34:49 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:52

FATIGUE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-20T21:34:13', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'f705bb24-b9cc-4d46-af89-57a41f8949ff' User entered 'None (0)' | (b) (4), (b) (6) System | 21 Aug 2020 02:34:49 |
| | System | 21 Aug 2020 02:34:49 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:52

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-20T21:34:16', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'f705bb24-b9cc-4d46-af89-57a41f8949ff' User entered 'None (0)' | (b) (4), (b) (6) System | 21 Aug 2020 02:34:49 |
| | System | 21 Aug 2020 02:34:49 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:52

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-20T21:34:20', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'f705bb24-b9cc-4d46-af89-57a41f8949ff' User entered 'None (0)' | (b) (4), (b) (6) System | 21 Aug 2020 02:34:49 |
| | System | 21 Aug 2020 02:34:49 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:52

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-20T21:34:23', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'f705bb24-b9cc-4d46-af89-57a41f8949ff' User entered 'None (0)' | (b) (4), (b) (6) System | 21 Aug 2020 02:34:49 |
| | System | 21 Aug 2020 02:34:49 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:52

CHILLS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-20T21:34:27', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'f705bb24-b9cc-4d46-af89-57a41f8949ff' | (b) (4), (b) (6) System | 21 Aug 2020 02:34:49 |
| User entered 'None (0)' | System | 21 Aug 2020 02:34:49 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:52

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) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-20T21:34:35', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'f705bb24-b9cc-4d46-af89-57a41f8949ff' | (b) (4), (b) (6) System | 21 Aug 2020 02:34:49 |
| User entered 'No (N)' | System | 21 Aug 2020 02:34:49 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:52

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-20T21:34:47', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'f705bb24-b9cc-4d46-af89-57a41f8949ff' User entered '20 Aug 2020 21:34' | (b) (4), (b) (6) System | 21 Aug 2020 02:34:49 |
| | System | 21 Aug 2020 02:34:49 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| User entered '20 Aug 2020 12:00' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| User entered '21 Aug 2020 11:59' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 17 Aug 2020 16:23:58 |
| User entered 'Day 5' | System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:52

HEADACHE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-21T20:58:48', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '9d8ca008-5630-4d57-ae46-a73cbca0164f' User entered 'None (0)' | (b) (4), (b) (6) System | 22 Aug 2020 01:59:31 |
| | System | 22 Aug 2020 01:59:31 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:52

FATIGUE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-21T20:58:54', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '9d8ca008-5630-4d57-ae46-a73cbca0164f' User entered 'None (0)' | (b) (4), (b) (6) System | 22 Aug 2020 01:59:31 |
| | System | 22 Aug 2020 01:59:31 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:52

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-21T20:58:58', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '9d8ca008-5630-4d57-ae46-a73cbca0164f' User entered 'None (0)' | (b) (4), (b) (6) System | 22 Aug 2020 01:59:31 |
| | System | 22 Aug 2020 01:59:31 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:52

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-21T20:59:01', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '9d8ca008-5630-4d57-ae46-a73cbca0164f' User entered 'None (0)' | (b) (4), (b) (6) System | 22 Aug 2020 01:59:31 |
| | System | 22 Aug 2020 01:59:31 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:52

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-21T20:59:04', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '9d8ca008-5630-4d57-ae46-a73cbca0164f' User entered 'None (0)' | (b) (4), (b) (6) System | 22 Aug 2020 01:59:31 |
| | System | 22 Aug 2020 01:59:31 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:52

CHILLS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-21T20:59:08', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '9d8ca008-5630-4d57-ae46-a73cbca0164f' User entered 'None (0)' | (b) (4), (b) (6) System | 22 Aug 2020 01:59:31 |
| | System | 22 Aug 2020 01:59:31 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:52

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) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-21T20:59:13', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '9d8ca008-5630-4d57-ae46-a73cbca0164f' User entered 'No (N)' | (b) (4), (b) (6) System | 22 Aug 2020 01:59:31 |
| | System | 22 Aug 2020 01:59:31 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:52

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-21T20:59:29', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '9d8ca008-5630-4d57-ae46-a73cbca0164f' User entered '21 Aug 2020 20:59' | (b) (4), (b) (6) System | 22 Aug 2020 01:59:31 |
| | System | 22 Aug 2020 01:59:31 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| User entered '21 Aug 2020 12:00' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| User entered '22 Aug 2020 11:59' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 17 Aug 2020 16:23:58 |
| User entered 'Day 6' | System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:52

HEADACHE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-22T21:44:47', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '3816b604-3783-41e5-9baa-dd425f10579a' User entered 'None (0)' | (b) (4), (b) (6) System | 23 Aug 2020 02:45:36 |
| | System | 23 Aug 2020 02:45:36 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:52

FATIGUE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-22T21:44:58', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '3816b604-3783-41e5-9baa-dd425f10579a' User entered 'None (0)' | (b) (4), (b) (6) System | 23 Aug 2020 02:45:36 |
| | System | 23 Aug 2020 02:45:36 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:52

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-22T21:45:03', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '3816b604-3783-41e5-9baa-dd425f10579a' User entered 'None (0)' | (b) (4), (b) (6) System | 23 Aug 2020 02:45:36 |
| | System | 23 Aug 2020 02:45:36 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:52

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-22T21:45:06', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '3816b604-3783-41e5-9baa-dd425f10579a' User entered 'None (0)' | (b) (4), (b) (6) System | 23 Aug 2020 02:45:36 |
| | System | 23 Aug 2020 02:45:36 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:52

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-22T21:45:10', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '3816b604-3783-41e5-9baa-dd425f10579a' User entered 'None (0)' | (b) (4), (b) (6) System | 23 Aug 2020 02:45:36 |
| | System | 23 Aug 2020 02:45:36 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:52

CHILLS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-22T21:45:13', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '3816b604-3783-41e5-9baa-dd425f10579a' User entered 'None (0)' | (b) (4), (b) (6) System | 23 Aug 2020 02:45:36 |
| | System | 23 Aug 2020 02:45:36 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:52

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) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-22T21:45:19', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '3816b604-3783-41e5-9baa-dd425f10579a' User entered 'No (N)' | (b) (4), (b) (6) System | 23 Aug 2020 02:45:36 |
| | System | 23 Aug 2020 02:45:36 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:52

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-22T21:45:31', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '3816b604-3783-41e5-9baa-dd425f10579a' User entered '22 Aug 2020 21:45' | (b) (4), (b) (6) System | 23 Aug 2020 02:45:36 |
| | System | 23 Aug 2020 02:45:36 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| User entered '22 Aug 2020 12:00' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| User entered '23 Aug 2020 11:59' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 17 Aug 2020 16:23:58 |
| User entered 'Day 7' | System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:52

HEADACHE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-23T21:42:04', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'dbc4566e-c759-4649-8db7-67e633fe6b4f' User entered 'None (0)' | (b) (4), (b) (6) System | 24 Aug 2020 02:42:49 |
| | System | 24 Aug 2020 02:42:49 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:52

FATIGUE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-23T21:42:12', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'dbc4566e-c759-4649-8db7-67e633fe6b4f' | (b) (4), (b) (6) | |
| | System | 24 Aug 2020 02:42:49 |
| User entered 'No interference with activity (1)' | System | 24 Aug 2020 02:42:49 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:52

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-23T21:42:17', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'dbc4566e-c759-4649-8db7-67e633fe6b4f' User entered 'None (0)' | (b) (4), (b) (6) System | 24 Aug 2020 02:42:49 |
| | System | 24 Aug 2020 02:42:49 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:52

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-23T21:42:22', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'dbc4566e-c759-4649-8db7-67e633fe6b4f' User entered 'None (0)' | (b) (4), (b) (6) System | 24 Aug 2020 02:42:49 |
| | System | 24 Aug 2020 02:42:49 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:52

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-23T21:42:25', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'dbc4566e-c759-4649-8db7-67e633fe6b4f' User entered 'None (0)' | (b) (4), (b) (6) System | 24 Aug 2020 02:42:49 |
| | System | 24 Aug 2020 02:42:49 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:52

CHILLS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-23T21:42:30', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'dbc4566e-c759-4649-8db7-67e633fe6b4f' User entered 'None (0)' | (b) (4), (b) (6) System | 24 Aug 2020 02:42:49 |
| | System | 24 Aug 2020 02:42:49 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:52

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) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-23T21:42:35', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'dbc4566e-c759-4649-8db7-67e633fe6b4f' User entered 'No (N)' | (b) (4), (b) (6) System | 24 Aug 2020 02:42:49 |
| | System | 24 Aug 2020 02:42:49 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:52

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-23T21:42:47', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'dbc4566e-c759-4649-8db7-67e633fe6b4f' User entered '23 Aug 2020 21:42' | (b) (4), (b) (6) System | 24 Aug 2020 02:42:49 |
| | System | 24 Aug 2020 02:42:49 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| User entered '23 Aug 2020 12:00' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| User entered '24 Aug 2020 11:59' | (b) (4), (b) (6) System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 24 Aug 2020 02:42:49 |
| User entered 'Day 8' | System | 24 Aug 2020 02:42:49 |

US3232056

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:05:52

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-24T13:26:20', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'a3da42f7-b9e4-4c07-b9c7-04dac570d186' | (b) (4), (b) (6) System | 24 Aug 2020 18:26:32 |
| User entered 'No interference with activity (1)' | System | 24 Aug 2020 18:26:32 |

US3232056

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:05:52

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-24T13:26:27', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'a3da42f7-b9e4-4c07-b9c7-04dac570d186' | (b) (4), (b) (6) | |
| | System | 24 Aug 2020 18:26:32 |
| User entered '24 Aug 2020 13:26' | System | 24 Aug 2020 18:26:32 |

US3232056

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| User entered '24 Aug 2020 12:00' | (b) (4), (b) (6) System | 24 Aug 2020 02:42:49 |

US3232056

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| User entered '25 Aug 2020 11:59' | (b) (4), (b) (6) System | 24 Aug 2020 02:42:49 |

US3232056

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 24 Aug 2020 02:42:49 |
| User entered 'Day 9' | System | 24 Aug 2020 02:42:49 |

US3232056

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 16:05:52

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-25T23:59:38', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '05d0f398-9f65-401e-8f3a-9d724d246fc8' | (b) (4), (b) (6) System | 26 Aug 2020 04:59:50 |
| User entered 'No interference with activity (1)' | System | 26 Aug 2020 04:59:50 |

US3232056

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 16:05:52

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-25T23:59:45', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '05d0f398-9f65-401e-8f3a-9d724d246fc8' User entered '25 Aug 2020 23:59' | (b) (4), (b) (6) System | 26 Aug 2020 04:59:50 |
| | System | 26 Aug 2020 04:59:50 |

US3232056

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| User entered '25 Aug 2020 12:00' | (b) (4), (b) (6) System | 24 Aug 2020 02:42:49 |

US3232056

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| User entered '26 Aug 2020 11:59' | (b) (4), (b) (6) System | 24 Aug 2020 02:42:49 |

US3232056

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 24 Aug 2020 18:26:32 |
| User entered 'Day 10' | System | 24 Aug 2020 18:26:32 |

US3232056

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 16:05:52

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-27T00:14:42', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '72ccea5e-9aa5-497f-b71e-bd1fb9046066' | (b) (4), (b) (6) System | 27 Aug 2020 05:14:50 |
| User entered 'No interference with activity (1)' | System | 27 Aug 2020 05:14:50 |

US3232056

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 16:05:52

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-27T00:14:46', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '72ccea5e-9aa5-497f-b71e-bd1fb9046066' User entered '27 Aug 2020 00:14' | (b) (4), (b) (6) System | 27 Aug 2020 05:14:50 |
| | System | 27 Aug 2020 05:14:50 |

US3232056

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| User entered '26 Aug 2020 12:00' | (b) (4), (b) (6) System | 24 Aug 2020 18:26:32 |

US3232056

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| User entered '27 Aug 2020 11:59' | (b) (4), (b) (6) System | 24 Aug 2020 18:26:32 |

US3232056

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 26 Aug 2020 04:59:50 |
| User entered 'Day 11' | System | 26 Aug 2020 04:59:50 |

US3232056

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 16:05:52

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-27T23:16:33', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '296fc5f9-6c5c-4526-8ed5-4258f56066da' | (b) (4), (b) (6) System | 28 Aug 2020 04:16:38 |
| User entered 'No interference with activity (1)' | System | 28 Aug 2020 04:16:38 |

US3232056

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 16:05:52

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-27T23:16:37', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '296fc5f9-6c5c-4526-8ed5-4258f56066da' User entered '27 Aug 2020 23:16' | (b) (4), (b) (6) System | 28 Aug 2020 04:16:38 |
| | System | 28 Aug 2020 04:16:38 |

US3232056

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| User entered '27 Aug 2020 12:00' | (b) (4), (b) (6) System | 26 Aug 2020 04:59:50 |

US3232056

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| User entered '28 Aug 2020 11:59' | (b) (4), (b) (6) System | 26 Aug 2020 04:59:50 |

US3232056

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 27 Aug 2020 05:14:50 |
| User entered 'Day 12' | System | 27 Aug 2020 05:14:50 |

US3232056

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 16:05:52

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-28T20:51:47', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '2c68f2f8-d519-4ecd-9bc8-55db7c686a88' User entered 'None (0)' | (b) (4), (b) (6) System | 29 Aug 2020 01:51:54 |
| | System | 29 Aug 2020 01:51:54 |

US3232056

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 16:05:52

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-28T20:51:51', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '2c68f2f8-d519-4ecd-9bc8-55db7c686a88' User entered '28 Aug 2020 20:51' | (b) (4), (b) (6) System | 29 Aug 2020 01:51:54 |
| | System | 29 Aug 2020 01:51:54 |

US3232056

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| User entered '28 Aug 2020 12:00' | (b) (4), (b) (6) System | 27 Aug 2020 05:14:50 |

US3232056

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 02:45:54 |
| User entered '29 Aug 2020 11:59' | (b) (4), (b) (6) System | 27 Aug 2020 05:14:50 |

US3232056

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 24 Aug 2020 02:42:49 |
| User entered 'Day 8' | System | 24 Aug 2020 02:42:49 |

US3232056

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:05:52

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) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-24T13:26:39', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '24488967-1a15-46a4-8e03-a1e60568234f' User entered 'No (N)' | (b) (4), (b) (6) System | 24 Aug 2020 18:26:46 |
| | System | 24 Aug 2020 18:26:46 |

US3232056

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:05:52

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-24T13:26:43', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '24488967-1a15-46a4-8e03-a1e60568234f' User entered '24 Aug 2020 13:26' | (b) (4), (b) (6) System | 24 Aug 2020 18:26:46 |
| | System | 24 Aug 2020 18:26:46 |

US3232056

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '24 Aug 2020 12:00' | (b) (4), (b) (6) System | 24 Aug 2020 02:42:49 |

US3232056

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '25 Aug 2020 11:59' | (b) (4), (b) (6) System | 24 Aug 2020 02:42:49 |

US3232056

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 24 Aug 2020 02:42:49 |
| User entered 'Day 9' | System | 24 Aug 2020 02:42:49 |

US3232056

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:05:52

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) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-25T23:59:54', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '0adf2541-b1f8-4f44-82fc-0f6a4cc22631' User entered 'No (N)' | (b) (4), (b) (6) System | 26 Aug 2020 05:00:03 |
| | System | 26 Aug 2020 05:00:03 |

US3232056

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:05:52

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-25T23:59:58', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '0adf2541-b1f8-4f44-82fc-0f6a4cc22631' User entered '25 Aug 2020 23:59' | (b) (4), (b) (6) System | 26 Aug 2020 05:00:03 |
| | System | 26 Aug 2020 05:00:03 |

US3232056

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '25 Aug 2020 12:00' | (b) (4), (b) (6) System | 24 Aug 2020 02:42:49 |

US3232056

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '26 Aug 2020 11:59' | (b) (4), (b) (6) System | 24 Aug 2020 02:42:49 |

US3232056

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 24 Aug 2020 18:26:32 |
| User entered 'Day 10' | System | 24 Aug 2020 18:26:32 |

US3232056

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:05:52

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) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-27T00:14:57', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'a18d142f-38aa-4174-82ff-7c8bb233603f' User entered 'No (N)' | (b) (4), (b) (6) System | 27 Aug 2020 05:15:06 |
| | System | 27 Aug 2020 05:15:06 |

US3232056

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:05:52

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-27T00:15:02', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'a18d142f-38aa-4174-82ff-7c8bb233603f' User entered '27 Aug 2020 00:15' | (b) (4), (b) (6) System | 27 Aug 2020 05:15:06 |
| | System | 27 Aug 2020 05:15:06 |

US3232056

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '26 Aug 2020 12:00' | (b) (4), (b) (6) System | 24 Aug 2020 18:26:32 |

US3232056

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '27 Aug 2020 11:59' | (b) (4), (b) (6) System | 24 Aug 2020 18:26:32 |

US3232056

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 26 Aug 2020 04:59:50 |
| User entered 'Day 11' | System | 26 Aug 2020 04:59:50 |

US3232056

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 16:05:52

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) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-27T23:16:44', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '09b2d348-e581-435b-89f4-1b402ea4c2de' User entered 'No (N)' | (b) (4), (b) (6) System | 28 Aug 2020 04:16:51 |
| | System | 28 Aug 2020 04:16:51 |

US3232056

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 16:05:52

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-27T23:16:48', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '09b2d348-e581-435b-89f4-1b402ea4c2de' User entered '27 Aug 2020 23:16' | (b) (4), (b) (6) System | 28 Aug 2020 04:16:51 |
| | System | 28 Aug 2020 04:16:51 |

US3232056

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '27 Aug 2020 12:00' | (b) (4), (b) (6) System | 26 Aug 2020 04:59:50 |

US3232056

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '28 Aug 2020 11:59' | (b) (4), (b) (6) System | 26 Aug 2020 04:59:50 |

US3232056

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 27 Aug 2020 05:14:50 |
| User entered 'Day 12' | System | 27 Aug 2020 05:14:50 |

US3232056

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 16:05:52

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) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-28T20:51:58', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '212d2375-1966-4e6a-a88d-203b5b0fcb6b' User entered 'No (N)' | (b) (4), (b) (6) System | 29 Aug 2020 01:52:05 |
| | System | 29 Aug 2020 01:52:05 |

US3232056

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 16:05:52

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-08-28T20:52:02', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '212d2375-1966-4e6a-a88d-203b5b0fcb6b' User entered '28 Aug 2020 20:52' | (b) (4), (b) (6) System | 29 Aug 2020 01:52:05 |
| | System | 29 Aug 2020 01:52:05 |

US3232056

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '28 Aug 2020 12:00' | (b) (4), (b) (6) System | 27 Aug 2020 05:14:50 |

US3232056

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '29 Aug 2020 11:59' | (b) (4), (b) (6) System | 27 Aug 2020 05:14:50 |

US3232056

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 26 Aug 2020 16:40:40 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '25 Aug 2020' | Adreanna Pou (b) (4) | 26 Aug 2020 16:40:40 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Contact Made (CONTACT MADE)' | Adreanna Pou (b) (4) | 26 Aug 2020 16:40:40 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 16:40:40 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:52

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 26 Aug 2020 16:40:45 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:52

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered 'I' | (b) (4), (b) (6) | 26 Aug 2020 16:40:45 |
| | System | |

US3232056

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 31 Aug 2020 21:20:04 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '31 Aug 2020' | Jerrica Sullivan (b) (4) | 31 Aug 2020 21:20:04 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Contact Made (CONTACT MADE)' | Jerrica Sullivan (b) (4) | 31 Aug 2020 21:20:04 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 31 Aug 2020 21:20:04 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:52

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 31 Aug 2020 21:21:59 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:52

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered 'I' | (b) (4), (b) (6) | 31 Aug 2020 21:21:59 |
| | System | |

US3232056

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 14 Sep 2020 16:14:40 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '8 Sep 2020' | Adreanna Pou (b) (4) | 14 Sep 2020 16:14:40 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Contact Made (CONTACT MADE)' | Adreanna Pou (b) (4) | 14 Sep 2020 16:14:40 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 14 Sep 2020 16:14:40 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:52

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 14 Sep 2020 16:14:43 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:52

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered 'I' | System | 14 Sep 2020 16:14:43 |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:52

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 14 Sep 2020 16:14:59 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:52

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '14 Sep 2020' | Adreanna Pou (b) (4) | 14 Sep 2020 16:14:59 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:52

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Clinic (Clinic)' | Adreanna Pou (b) (4) | 14 Sep 2020 16:14:59 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:52

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered 'VISIT2' | System | 14 Sep 2020 16:14:59 |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

[Timepoint](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User accepted default value 'Pre-Dose (PREDOSE)' | Adreanna Pou (b) (4) | 14 Sep 2020 16:16:29 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 14 Sep 2020 16:16:29 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '14 Sep 2020' | Adreanna Pou (b) (4) | 14 Sep 2020 16:16:29 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '09:05' | Adreanna Pou (b) (4) | 14 Sep 2020 16:16:29 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered '14 Sep 2020 09:05' | (b) (4), (b) (6) | |
| | System | 14 Sep 2020 16:16:29 |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '99.1' F | Adreanna Pou (b) (4) | 14 Sep 2020 16:16:29 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Oral (Oral)' | Adreanna Pou (b) (4) | 14 Sep 2020 16:16:29 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 14 Sep 2020 16:16:29 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '76' | Adreanna Pou (b) (4) | 14 Sep 2020 16:16:29 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered 'bpm' | System | 14 Sep 2020 16:16:29 |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '20' | Adreanna Pou (b) (4) | 14 Sep 2020 16:16:29 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered 'breaths/min' | (b) (4), (b) (6) | 14 Sep 2020 16:16:29 |
| | System | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '114' | Adreanna Pou (b) (4) | 14 Sep 2020 16:16:29 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered 'mmHg' | (b) (4), (b) (6) System | 14 Sep 2020 16:16:29 |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '67' | Adreanna Pou (b) (4) | 14 Sep 2020 16:16:29 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered 'mmHg' | (b) (4), (b) (6) System | 14 Sep 2020 16:16:29 |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

[Timepoint](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User accepted default value 'Post-Dose (POSTDOSE)' | Adreanna Pou (b) (4) | 14 Sep 2020 16:16:29 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 14 Sep 2020 16:16:29 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '14 Sep 2020' | Adreanna Pou (b) (4) | 14 Sep 2020 16:16:29 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '10:20' | Adreanna Pou (b) (4) | 14 Sep 2020 16:16:29 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered '14 Sep 2020 10:20' | (b) (4), (b) (6) | 14 Sep 2020 16:16:29 |
| | System | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '97.5' F | Adreanna Pou (b) (4) | 14 Sep 2020 16:16:29 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

[Route of measurement](#)

| Audit | User | Time (GMT) |
|------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Other (Other)' | Adreanna Pou (b) (4) | 14 Sep 2020 16:16:29 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'temporal' | Adreanna Pou (b) (4) | 14 Sep 2020 16:16:29 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '69' | Adreanna Pou (b) (4) | 14 Sep 2020 16:16:29 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered 'bpm' | System | 14 Sep 2020 16:16:29 |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '18' | Adreanna Pou (b) (4) | 14 Sep 2020 16:16:29 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered 'breaths/min' | (b) (4), (b) (6) | 14 Sep 2020 16:16:29 |
| | System | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '115' | Adreanna Pou (b) (4) | 14 Sep 2020 16:16:29 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered 'mmHg' | (b) (4), (b) (6) System | 14 Sep 2020 16:16:29 |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '64' | Adreanna Pou (b) (4) | 14 Sep 2020 16:16:29 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered 'mmHg' | (b) (4), (b) (6) System | 14 Sep 2020 16:16:29 |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:52

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 14 Sep 2020 16:16:39 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:52

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '14 Sep 2020' | Adreanna Pou (b) (4) | 14 Sep 2020 16:16:39 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:52

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 14 Sep 2020 16:17:21 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:52

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 14 Sep 2020 16:17:21 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:52

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 14 Sep 2020 16:17:21 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:52

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered 'MRNA-1273 OR PLACEBO' | (b) (4), (b) (6) | 14 Sep 2020 16:17:21 |
| | System | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:52

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '14 Sep 2020' | Adreanna Pou (b) (4) | 14 Sep 2020 16:17:21 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:52

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '09:54' | Adreanna Pou (b) (4) | 14 Sep 2020 16:17:21 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:52

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered '14 Sep 2020 09:54' | (b) (4), (b) (6) | 14 Sep 2020 16:17:21 |
| | System | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:52

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Left Arm (LEFT ARM)' | Adreanna Pou (b) (4) | 14 Sep 2020 16:17:21 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:52

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered 'ONCE' | System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:52

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered 'INTRAMUSCULAR' | (b) (4), (b) (6) | 14 Sep 2020 16:17:21 |
| | System | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:52

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 14 Sep 2020 16:17:52 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:52

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '14 Sep 2020' | Adreanna Pou (b) (4) | 14 Sep 2020 16:17:52 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:52

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '09:08' | Adreanna Pou (b) (4) | 14 Sep 2020 16:17:52 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:52

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered '14 Sep 2020 09:08' | (b) (4), (b) (6) | 14 Sep 2020 16:17:52 |
| | System | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:05:52

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '14 Sep 2020' | Adreanna Pou (b) (4) | 14 Sep 2020 16:18:07 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:52

[Lab Test](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Adreanna Pou (b) (4) | 14 Sep 2020 16:18:07 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:52

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 14 Sep 2020 16:18:07 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:52

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '09:06' | Adreanna Pou (b) (4) | 14 Sep 2020 16:18:07 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:52

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered '14 Sep 2020 09:06' | (b) (4), (b) (6) | |
| | System | 14 Sep 2020 16:18:07 |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:52

[Lab Test](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Adreanna Pou (b) (4) | 14 Sep 2020 16:18:07 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:52

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 14 Sep 2020 16:18:07 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:52

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 14 Sep 2020 16:18:07 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:52

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered empty. | (b) (4), (b) (6) | |
| | System | 14 Sep 2020 16:18:07 |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:52

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 14 Sep 2020 16:18:11 |
| | (b) (4) | |

US3232056

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:52

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered '1' | (b) (4), (b) (6) | 14 Sep 2020 16:18:11 |
| | System | |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| Data entry locked. | (b) (4), (b) (6) | |
| | System | 14 Sep 2020 16:17:21 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|-------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|-------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|-------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

To **TREAT** pain or fever that has already occurred

| Audit | User | Time (GMT) |
|-------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|-------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '14 Sep 2020 10:14' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '14 Sep 2020 12:44' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|---------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| Data entry locked. | (b) (4), (b) (6) | |
| | System | 14 Sep 2020 16:17:21 |
| User entered 'Day 1, after vaccination (at home)' | System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-14T21:17:31', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'fb63512e-e823-4913-b5f7-c792aaedab90' User entered 'Yes (Y)' | (b) (4), (b) (6) System | 15 Sep 2020 02:18:00 |
| | System | 15 Sep 2020 02:18:00 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-14T21:17:40', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'fb63512e-e823-4913-b5f7-c792aaedab90' User entered '98.3' | (b) (4), (b) (6) System | 15 Sep 2020 02:18:00 |
| | System | 15 Sep 2020 02:18:00 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-14T21:17:47', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'fb63512e-e823-4913-b5f7-c792aaedab90' | (b) (4), (b) (6) System | 15 Sep 2020 02:18:00 |
| User entered 'No (N)' | System | 15 Sep 2020 02:18:00 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-14T21:17:56', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'fb63512e-e823-4913-b5f7-c792aaedab90' User entered '14 Sep 2020 21:17' | (b) (4), (b) (6) System | 15 Sep 2020 02:18:00 |
| | System | 15 Sep 2020 02:18:00 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '14 Sep 2020 13:39' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '15 Sep 2020 11:59' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| Data entry locked. | (b) (4), (b) (6) | |
| | System | 14 Sep 2020 16:17:21 |
| User entered 'Day 2' | System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:52

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-15T21:25:50', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'c9ad9aab-a45c-4199-9ab6-7de9e23763a0' User entered 'Yes (Y)' | (b) (4), (b) (6) System | 16 Sep 2020 02:26:14 |
| | System | 16 Sep 2020 02:26:14 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:52

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-15T21:25:57', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'c9ad9aab-a45c-4199-9ab6-7de9e23763a0' User entered '98.2' | (b) (4), (b) (6) System | 16 Sep 2020 02:26:14 |
| | System | 16 Sep 2020 02:26:14 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:52

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-15T21:26:03', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'c9ad9aab-a45c-4199-9ab6-7de9e23763a0' | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 16 Sep 2020 02:26:14 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:52

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-15T21:26:10', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'c9ad9aab-a45c-4199-9ab6-7de9e23763a0' | (b) (4), (b) (6) System | 16 Sep 2020 02:26:14 |
| User entered '15 Sep 2020 21:26' | System | 16 Sep 2020 02:26:14 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '15 Sep 2020 12:00' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '16 Sep 2020 11:59' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| Data entry locked. | (b) (4), (b) (6) | |
| | System | 14 Sep 2020 16:17:21 |
| User entered 'Day 3' | System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:52

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-16T21:17:51', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '3401d634-0017-40a5-818c-16f14e2f405d' User entered 'Yes (Y)' | (b) (4), (b) (6) System | 17 Sep 2020 02:18:09 |
| | System | 17 Sep 2020 02:18:09 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:52

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-16T21:17:56', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '3401d634-0017-40a5-818c-16f14e2f405d' User entered '99.0' | (b) (4), (b) (6) System | 17 Sep 2020 02:18:09 |
| | System | 17 Sep 2020 02:18:09 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:52

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-16T21:18:02', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '3401d634-0017-40a5-818c-16f14e2f405d' User entered 'No (N)' | (b) (4), (b) (6) System | 17 Sep 2020 02:18:09 |
| | System | 17 Sep 2020 02:18:09 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:52

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-16T21:18:08', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '3401d634-0017-40a5-818c-16f14e2f405d' User entered '16 Sep 2020 21:18' | (b) (4), (b) (6) System | 17 Sep 2020 02:18:09 |
| | System | 17 Sep 2020 02:18:09 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '16 Sep 2020 12:00' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '17 Sep 2020 11:59' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| Data entry locked. | (b) (4), (b) (6) | |
| | System | 14 Sep 2020 16:17:21 |
| User entered 'Day 4' | System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:52

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-18T00:02:18', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '0f631787-ff13-4182-a294-be23d96812e0' User entered 'Yes (Y)' | (b) (4), (b) (6) System | 18 Sep 2020 05:02:41 |
| | System | 18 Sep 2020 05:02:41 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:52

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-18T00:02:25', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '0f631787-ff13-4182-a294-be23d96812e0' User entered '98.8' | (b) (4), (b) (6) System | 18 Sep 2020 05:02:41 |
| | System | 18 Sep 2020 05:02:41 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:52

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-18T00:02:30', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '0f631787-ff13-4182-a294-be23d96812e0' | (b) (4), (b) (6) | |
| | System | 18 Sep 2020 05:02:41 |
| User entered 'No (N)' | System | 18 Sep 2020 05:02:41 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:52

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-18T00:02:37', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '0f631787-ff13-4182-a294-be23d96812e0' User entered '18 Sep 2020 00:02' | (b) (4), (b) (6) System | 18 Sep 2020 05:02:41 |
| | System | 18 Sep 2020 05:02:41 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '17 Sep 2020 12:00' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '18 Sep 2020 11:59' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| Data entry locked. | (b) (4), (b) (6) | |
| | System | 14 Sep 2020 16:17:21 |
| User entered 'Day 5' | System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:52

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-18T21:27:47', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '649630ea-c817-4b7c-9193-11a12262e668' User entered 'Yes (Y)' | (b) (4), (b) (6) System | 19 Sep 2020 02:37:35 |
| | System | 19 Sep 2020 02:37:35 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:52

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-18T21:27:53', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '649630ea-c817-4b7c-9193-11a12262e668' User entered '98.2' | (b) (4), (b) (6) System | 19 Sep 2020 02:37:35 |
| | System | 19 Sep 2020 02:37:35 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:52

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-18T21:27:57', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '649630ea-c817-4b7c-9193-11a12262e668' User entered 'No (N)' | (b) (4), (b) (6) System | 19 Sep 2020 02:37:35 |
| | System | 19 Sep 2020 02:37:35 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:52

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-18T21:28:08', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '649630ea-c817-4b7c-9193-11a12262e668' User entered '18 Sep 2020 21:28' | (b) (4), (b) (6) System | 19 Sep 2020 02:37:35 |
| | System | 19 Sep 2020 02:37:35 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '18 Sep 2020 12:00' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '19 Sep 2020 11:59' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| Data entry locked. | (b) (4), (b) (6) | |
| | System | 14 Sep 2020 16:17:21 |
| User entered 'Day 6' | System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:52

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-19T22:21:36', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '3990fc88-e82f-4779-a307-8ae959d6a07e' User entered 'Yes (Y)' | (b) (4), (b) (6) System | 20 Sep 2020 03:22:17 |
| | System | 20 Sep 2020 03:22:17 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:52

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-19T22:21:43', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '3990fc88-e82f-4779-a307-8ae959d6a07e' User entered '98.5' | (b) (4), (b) (6) System | 20 Sep 2020 03:22:17 |
| | System | 20 Sep 2020 03:22:17 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:52

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-19T22:21:49', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '3990fc88-e82f-4779-a307-8ae959d6a07e' User entered 'Yes (Y)' | (b) (4), (b) (6) System | 20 Sep 2020 03:22:17 |
| | System | 20 Sep 2020 03:22:17 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:52

To **TREAT** pain or fever that has already occurred

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| 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 'no medication taken per patient report ' (Site from System). | (b) (4), (b) (6) | 01 Nov 2020 14:08:57 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-19T22:22:01', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '3990fc88-e82f-4779-a307-8ae959d6a07e' User entered '1' | Jerrica Sullivan (b) (4) | 27 Oct 2020 15:55:28 |
| | System | 20 Sep 2020 03:22:17 |
| | System | 20 Sep 2020 03:22:17 |
| | System | 20 Sep 2020 03:22:17 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:52

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-19T22:22:01', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '3990fc88-e82f-4779-a307-8ae959d6a07e' User entered '0' | (b) (4), (b) (6) System | 20 Sep 2020 03:22:17 |
| | System | 20 Sep 2020 03:22:17 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:52

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-19T22:22:15', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '3990fc88-e82f-4779-a307-8ae959d6a07e' User entered '19 Sep 2020 22:22' | (b) (4), (b) (6) System | 20 Sep 2020 03:22:17 |
| | System | 20 Sep 2020 03:22:17 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '19 Sep 2020 12:00' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '20 Sep 2020 11:59' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| Data entry locked. | (b) (4), (b) (6) | |
| | System | 14 Sep 2020 16:17:21 |
| User entered 'Day 7' | System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:52

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-20T20:57:55', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '88fe7dd6-502c-4aed-a930-b958c9c183ae' User entered 'Yes (Y)' | (b) (4), (b) (6) System | 21 Sep 2020 01:58:27 |
| | System | 21 Sep 2020 01:58:27 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:52

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-20T20:58:03', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '88fe7dd6-502c-4aed-a930-b958c9c183ae' User entered '98.8' | (b) (4), (b) (6) System | 21 Sep 2020 01:58:27 |
| | System | 21 Sep 2020 01:58:27 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:52

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-20T20:58:07', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '88fe7dd6-502c-4aed-a930-b958c9c183ae' User entered 'No (N)' | (b) (4), (b) (6) System | 21 Sep 2020 01:58:27 |
| | System | 21 Sep 2020 01:58:27 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:52

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-20T20:58:24', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '88fe7dd6-502c-4aed-a930-b958c9c183ae' User entered '20 Sep 2020 20:58' | (b) (4), (b) (6) System | 21 Sep 2020 01:58:27 |
| | System | 21 Sep 2020 01:58:27 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '20 Sep 2020 12:00' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '21 Sep 2020 11:59' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| Data entry locked. | (b) (4), (b) (6) | |
| | System | 14 Sep 2020 16:17:21 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

Is there any **REDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|-------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

| Audit | User | Time (GMT) |
|-------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|-------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

| Audit | User | Time (GMT) |
|-------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '14 Sep 2020 10:14' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '14 Sep 2020 12:44' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|---------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| Data entry locked. | (b) (4), (b) (6) | |
| | System | 14 Sep 2020 16:17:21 |
| User entered 'Day 1, after vaccination (at home)' | System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-14T21:18:27', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'ca9ad7f2-2f13-4d17-a240-b4c1465b043b' User entered 'None (1)' | (b) (4), (b) (6) System | 15 Sep 2020 02:19:01 |
| | System | 15 Sep 2020 02:19:01 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-14T21:18:32', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'ca9ad7f2-2f13-4d17-a240-b4c1465b043b' User entered 'No (N)' | (b) (4), (b) (6) System | 15 Sep 2020 02:19:01 |
| | System | 15 Sep 2020 02:19:01 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-14T21:18:39', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'ca9ad7f2-2f13-4d17-a240-b4c1465b043b' User entered 'No (N)' | (b) (4), (b) (6) System | 15 Sep 2020 02:19:01 |
| | System | 15 Sep 2020 02:19:01 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-14T21:18:48', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'ca9ad7f2-2f13-4d17-a240-b4c1465b043b' User entered 'None (1)' | (b) (4), (b) (6) System | 15 Sep 2020 02:19:01 |
| | System | 15 Sep 2020 02:19:01 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-14T21:18:57', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'ca9ad7f2-2f13-4d17-a240-b4c1465b043b' User entered '14 Sep 2020 21:18' | (b) (4), (b) (6) System | 15 Sep 2020 02:19:01 |
| | System | 15 Sep 2020 02:19:01 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '14 Sep 2020 13:39' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '15 Sep 2020 11:59' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| Data entry locked. | (b) (4), (b) (6) | |
| | System | 14 Sep 2020 16:17:21 |
| User entered 'Day 2' | System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:52

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-15T21:26:20', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'c943de78-2dc4-48fb-bb49-329b34c3b6e1' User entered 'None (1)' | (b) (4), (b) (6) System | 16 Sep 2020 02:26:59 |
| | System | 16 Sep 2020 02:26:59 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:52

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-15T21:26:25', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'c943de78-2dc4-48fb-bb49-329b34c3b6e1' User entered 'No (N)' | (b) (4), (b) (6) System | 16 Sep 2020 02:26:59 |
| | System | 16 Sep 2020 02:26:59 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-15T21:26:29', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'c943de78-2dc4-48fb-bb49-329b34c3b6e1' User entered 'No (N)' | (b) (4), (b) (6) System | 16 Sep 2020 02:26:59 |
| | System | 16 Sep 2020 02:26:59 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:52

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-15T21:26:41', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'c943de78-2dc4-48fb-bb49-329b34c3b6e1' User entered 'None (1)' | (b) (4), (b) (6) System | 16 Sep 2020 02:26:59 |
| | System | 16 Sep 2020 02:26:59 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:52

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-15T21:26:54', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'c943de78-2dc4-48fb-bb49-329b34c3b6e1' User entered '15 Sep 2020 21:26' | (b) (4), (b) (6) System | 16 Sep 2020 02:26:59 |
| | System | 16 Sep 2020 02:26:59 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '15 Sep 2020 12:00' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '16 Sep 2020 11:59' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| Data entry locked. | (b) (4), (b) (6) | |
| | System | 14 Sep 2020 16:17:21 |
| User entered 'Day 3' | System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:52

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-16T21:18:14', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'cda6a2cb-8ef6-4327-937f-7583be467b73' User entered 'None (1)' | (b) (4), (b) (6) System | 17 Sep 2020 02:18:53 |
| | System | 17 Sep 2020 02:18:53 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:52

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-16T21:18:21', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'cda6a2cb-8ef6-4327-937f-7583be467b73' User entered 'No (N)' | (b) (4), (b) (6) System | 17 Sep 2020 02:18:53 |
| | System | 17 Sep 2020 02:18:53 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-16T21:18:25', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'cda6a2cb-8ef6-4327-937f-7583be467b73' User entered 'No (N)' | (b) (4), (b) (6) System | 17 Sep 2020 02:18:53 |
| | System | 17 Sep 2020 02:18:53 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:52

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-16T21:18:36', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'cda6a2cb-8ef6-4327-937f-7583be467b73' User entered 'None (1)' | (b) (4), (b) (6) System | 17 Sep 2020 02:18:53 |
| | System | 17 Sep 2020 02:18:53 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:52

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-16T21:18:50', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'cda6a2cb-8ef6-4327-937f-7583be467b73' User entered '16 Sep 2020 21:18' | (b) (4), (b) (6) System | 17 Sep 2020 02:18:53 |
| | System | 17 Sep 2020 02:18:53 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '16 Sep 2020 12:00' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '17 Sep 2020 11:59' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| Data entry locked. | (b) (4), (b) (6) | |
| | System | 14 Sep 2020 16:17:21 |
| User entered 'Day 4' | System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:52

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-18T00:02:43', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '1ae2b89b-a8db-4763-b96e-0f2d0d0c5947' | (b) (4), (b) (6) System | 18 Sep 2020 05:03:09 |
| User entered 'None (1)' | System | 18 Sep 2020 05:03:09 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:52

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-18T00:02:47', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '1ae2b89b-a8db-4763-b96e-0f2d0d0c5947' User entered 'No (N)' | (b) (4), (b) (6) System | 18 Sep 2020 05:03:09 |
| | System | 18 Sep 2020 05:03:09 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-18T00:02:50', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '1ae2b89b-a8db-4763-b96e-0f2d0d0c5947' User entered 'No (N)' | (b) (4), (b) (6) System | 18 Sep 2020 05:03:09 |
| | System | 18 Sep 2020 05:03:09 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:52

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-18T00:02:56', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '1ae2b89b-a8db-4763-b96e-0f2d0d0c5947' | (b) (4), (b) (6) System | 18 Sep 2020 05:03:09 |
| User entered 'None (1)' | System | 18 Sep 2020 05:03:09 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:52

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-18T00:03:06', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '1ae2b89b-a8db-4763-b96e-0f2d0d0c5947' User entered '18 Sep 2020 00:03' | (b) (4), (b) (6) System | 18 Sep 2020 05:03:09 |
| | System | 18 Sep 2020 05:03:09 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '17 Sep 2020 12:00' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '18 Sep 2020 11:59' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| Data entry locked. | (b) (4), (b) (6) | |
| | System | 14 Sep 2020 16:17:21 |
| User entered 'Day 5' | System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:52

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-18T21:28:14', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '2b74ee1d-54fb-42b7-89f3-ab2e84bfe9f9' | (b) (4), (b) (6) System | 19 Sep 2020 02:37:41 |
| User entered 'None (1)' | System | 19 Sep 2020 02:37:41 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:52

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-18T21:28:17', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '2b74ee1d-54fb-42b7-89f3-ab2e84bfe9f9' User entered 'No (N)' | (b) (4), (b) (6) System | 19 Sep 2020 02:37:41 |
| | System | 19 Sep 2020 02:37:41 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-18T21:28:20', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '2b74ee1d-54fb-42b7-89f3-ab2e84bfe9f9' User entered 'No (N)' | (b) (4), (b) (6) System | 19 Sep 2020 02:37:41 |
| | System | 19 Sep 2020 02:37:41 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:52

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-18T21:28:24', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '2b74ee1d-54fb-42b7-89f3-ab2e84bfe9f9' | (b) (4), (b) (6) System | 19 Sep 2020 02:37:41 |
| User entered 'None (1)' | System | 19 Sep 2020 02:37:41 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:52

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-18T21:28:45', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '2b74ee1d-54fb-42b7-89f3-ab2e84bfe9f9' User entered '18 Sep 2020 21:28' | (b) (4), (b) (6) System | 19 Sep 2020 02:37:41 |
| | System | 19 Sep 2020 02:37:41 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '18 Sep 2020 12:00' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '19 Sep 2020 11:59' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| Data entry locked. | (b) (4), (b) (6) | |
| | System | 14 Sep 2020 16:17:21 |
| User entered 'Day 6' | System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:52

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-19T22:22:21', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '93f5aba0-3db2-46dc-84a6-ea2c8f65138a' User entered 'None (1)' | (b) (4), (b) (6) System | 20 Sep 2020 03:22:45 |
| | System | 20 Sep 2020 03:22:45 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:52

Is there any **REDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-19T22:22:24', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '93f5aba0-3db2-46dc-84a6-ea2c8f65138a' User entered 'No (N)' | (b) (4), (b) (6) System | 20 Sep 2020 03:22:45 |
| | System | 20 Sep 2020 03:22:45 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-19T22:22:28', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '93f5aba0-3db2-46dc-84a6-ea2c8f65138a' User entered 'No (N)' | (b) (4), (b) (6) System | 20 Sep 2020 03:22:45 |
| | System | 20 Sep 2020 03:22:45 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:52

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-19T22:22:33', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '93f5aba0-3db2-46dc-84a6-ea2c8f65138a' User entered 'None (1)' | (b) (4), (b) (6) System | 20 Sep 2020 03:22:45 |
| | System | 20 Sep 2020 03:22:45 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:52

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-19T22:22:42', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '93f5aba0-3db2-46dc-84a6-ea2c8f65138a' User entered '19 Sep 2020 22:22' | (b) (4), (b) (6) System | 20 Sep 2020 03:22:45 |
| | System | 20 Sep 2020 03:22:45 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '19 Sep 2020 12:00' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '20 Sep 2020 11:59' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| Data entry locked. | (b) (4), (b) (6) | |
| | System | 14 Sep 2020 16:17:21 |
| User entered 'Day 7' | System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:52

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-20T20:58:31', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'a878d2fa-a18c-43db-a923-89f0aeb9c22a' User entered 'None (1)' | (b) (4), (b) (6) System | 21 Sep 2020 01:58:52 |
| | System | 21 Sep 2020 01:58:52 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:52

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-20T20:58:35', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'a878d2fa-a18c-43db-a923-89f0aeb9c22a' User entered 'No (N)' | (b) (4), (b) (6) System | 21 Sep 2020 01:58:52 |
| | System | 21 Sep 2020 01:58:52 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-20T20:58:39', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'a878d2fa-a18c-43db-a923-89f0aeb9c22a' User entered 'No (N)' | (b) (4), (b) (6) System | 21 Sep 2020 01:58:52 |
| | System | 21 Sep 2020 01:58:52 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:52

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-20T20:58:43', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'a878d2fa-a18c-43db-a923-89f0aeb9c22a' User entered 'None (1)' | (b) (4), (b) (6) System | 21 Sep 2020 01:58:52 |
| | System | 21 Sep 2020 01:58:52 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:52

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-20T20:58:50', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'a878d2fa-a18c-43db-a923-89f0aeb9c22a' User entered '20 Sep 2020 20:58' | (b) (4), (b) (6) System | 21 Sep 2020 01:58:52 |
| | System | 21 Sep 2020 01:58:52 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '20 Sep 2020 12:00' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '21 Sep 2020 11:59' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| Data entry locked. | (b) (4), (b) (6) | |
| | System | 14 Sep 2020 16:17:21 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

HEADACHE

| Audit | User | Time (GMT) |
|-------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

FATIGUE

| Audit | User | Time (GMT) |
|-------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|-------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|-------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|-------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

CHILLS

| Audit | User | Time (GMT) |
|-------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|-------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '14 Sep 2020 10:14' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '14 Sep 2020 12:44' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|---------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| Data entry locked. | (b) (4), (b) (6) | |
| | System | 14 Sep 2020 16:17:21 |
| User entered 'Day 1, after vaccination (at home)' | System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

HEADACHE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-14T21:19:06', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '40d79d14-db20-486f-be10-9ce3a5145c2f' User entered 'None (0)' | (b) (4), (b) (6) System | 15 Sep 2020 02:19:55 |
| | System | 15 Sep 2020 02:19:55 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

FATIGUE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-14T21:19:10', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '40d79d14-db20-486f-be10-9ce3a5145c2f' User entered 'None (0)' | (b) (4), (b) (6) System | 15 Sep 2020 02:19:55 |
| | System | 15 Sep 2020 02:19:55 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-14T21:19:15', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '40d79d14-db20-486f-be10-9ce3a5145c2f' User entered 'None (0)' | (b) (4), (b) (6) System | 15 Sep 2020 02:19:55 |
| | System | 15 Sep 2020 02:19:55 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-14T21:19:21', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '40d79d14-db20-486f-be10-9ce3a5145c2f' User entered 'None (0)' | (b) (4), (b) (6) System | 15 Sep 2020 02:19:55 |
| | System | 15 Sep 2020 02:19:55 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-14T21:19:26', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '40d79d14-db20-486f-be10-9ce3a5145c2f' User entered 'None (0)' | (b) (4), (b) (6) System | 15 Sep 2020 02:19:55 |
| | System | 15 Sep 2020 02:19:55 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

CHILLS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-14T21:19:31', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '40d79d14-db20-486f-be10-9ce3a5145c2f' User entered 'None (0)' | (b) (4), (b) (6) System | 15 Sep 2020 02:19:55 |
| | System | 15 Sep 2020 02:19:55 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

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) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-14T21:19:36', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '40d79d14-db20-486f-be10-9ce3a5145c2f' User entered 'No (N)' | (b) (4), (b) (6) System | 15 Sep 2020 02:19:55 |
| | System | 15 Sep 2020 02:19:55 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-14T21:19:50', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '40d79d14-db20-486f-be10-9ce3a5145c2f' User entered '14 Sep 2020 21:19' | (b) (4), (b) (6) System | 15 Sep 2020 02:19:55 |
| | System | 15 Sep 2020 02:19:55 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '14 Sep 2020 13:39' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '15 Sep 2020 11:59' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| Data entry locked. | (b) (4), (b) (6) | |
| | System | 14 Sep 2020 16:17:21 |
| User entered 'Day 2' | System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:52

HEADACHE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-15T21:27:02', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '2b453e3f-2bdd-4681-bcb1-e1f0713dd37e' User entered 'None (0)' | (b) (4), (b) (6) System | 16 Sep 2020 02:28:00 |
| | System | 16 Sep 2020 02:28:00 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:52

FATIGUE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-15T21:27:07', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '2b453e3f-2bdd-4681-bcb1-e1f0713dd37e' User entered 'None (0)' | (b) (4), (b) (6) System | 16 Sep 2020 02:28:00 |
| | System | 16 Sep 2020 02:28:00 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:52

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-15T21:27:11', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '2b453e3f-2bdd-4681-bcb1-e1f0713dd37e' User entered 'None (0)' | (b) (4), (b) (6) System | 16 Sep 2020 02:28:00 |
| | System | 16 Sep 2020 02:28:00 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:52

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-15T21:27:15', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '2b453e3f-2bdd-4681-bcb1-e1f0713dd37e' User entered 'None (0)' | (b) (4), (b) (6) System | 16 Sep 2020 02:28:00 |
| | System | 16 Sep 2020 02:28:00 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:52

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-15T21:27:21', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '2b453e3f-2bdd-4681-bcb1-e1f0713dd37e' User entered 'None (0)' | (b) (4), (b) (6) System | 16 Sep 2020 02:28:00 |
| | System | 16 Sep 2020 02:28:00 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:52

CHILLS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-15T21:27:24', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '2b453e3f-2bdd-4681-bcb1-e1f0713dd37e' User entered 'None (0)' | (b) (4), (b) (6) System | 16 Sep 2020 02:28:00 |
| | System | 16 Sep 2020 02:28:00 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:52

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) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-15T21:27:35', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '2b453e3f-2bdd-4681-bcb1-e1f0713dd37e' User entered 'No (N)' | (b) (4), (b) (6) System | 16 Sep 2020 02:28:00 |
| | System | 16 Sep 2020 02:28:00 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:52

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-15T21:27:56', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '2b453e3f-2bdd-4681-bcb1-e1f0713dd37e' User entered '15 Sep 2020 21:27' | (b) (4), (b) (6) System | 16 Sep 2020 02:28:00 |
| | System | 16 Sep 2020 02:28:00 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '15 Sep 2020 12:00' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '16 Sep 2020 11:59' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| Data entry locked. | (b) (4), (b) (6) | |
| | System | 14 Sep 2020 16:17:21 |
| User entered 'Day 3' | System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:52

HEADACHE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-16T21:18:58', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'a11e2440-90b7-4898-9bea-f25d8d2ef9ed' User entered 'None (0)' | (b) (4), (b) (6) System | 17 Sep 2020 02:19:37 |
| | System | 17 Sep 2020 02:19:37 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:52

FATIGUE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-16T21:19:01', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'a11e2440-90b7-4898-9bea-f25d8d2ef9ed' User entered 'None (0)' | (b) (4), (b) (6) System | 17 Sep 2020 02:19:37 |
| | System | 17 Sep 2020 02:19:37 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:52

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-16T21:19:04', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'a11e2440-90b7-4898-9bea-f25d8d2ef9ed' User entered 'None (0)' | (b) (4), (b) (6) System | 17 Sep 2020 02:19:37 |
| | System | 17 Sep 2020 02:19:37 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:52

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-16T21:19:09', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'a11e2440-90b7-4898-9bea-f25d8d2ef9ed' User entered 'None (0)' | (b) (4), (b) (6) System | 17 Sep 2020 02:19:37 |
| | System | 17 Sep 2020 02:19:37 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:52

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-16T21:19:13', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'a11e2440-90b7-4898-9bea-f25d8d2ef9ed' User entered 'None (0)' | (b) (4), (b) (6) System | 17 Sep 2020 02:19:37 |
| | System | 17 Sep 2020 02:19:37 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:52

CHILLS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-16T21:19:17', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'a11e2440-90b7-4898-9bea-f25d8d2ef9ed' User entered 'None (0)' | (b) (4), (b) (6) System | 17 Sep 2020 02:19:37 |
| | System | 17 Sep 2020 02:19:37 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:52

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) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-16T21:19:22', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'a11e2440-90b7-4898-9bea-f25d8d2ef9ed' | (b) (4), (b) (6) System | 17 Sep 2020 02:19:37 |
| User entered 'No (N)' | System | 17 Sep 2020 02:19:37 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:52

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-16T21:19:34', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'a11e2440-90b7-4898-9bea-f25d8d2ef9ed' User entered '16 Sep 2020 21:19' | (b) (4), (b) (6) System | 17 Sep 2020 02:19:37 |
| | System | 17 Sep 2020 02:19:37 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '16 Sep 2020 12:00' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '17 Sep 2020 11:59' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| Data entry locked. | (b) (4), (b) (6) | |
| | System | 14 Sep 2020 16:17:21 |
| User entered 'Day 4' | System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:52

HEADACHE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-18T00:03:13', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '9c1428f7-c53b-4b80-b81c-6993760c1882' User entered 'None (0)' | (b) (4), (b) (6) System | 18 Sep 2020 05:03:58 |
| | System | 18 Sep 2020 05:03:58 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:52

FATIGUE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-18T00:03:18', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '9c1428f7-c53b-4b80-b81c-6993760c1882' User entered 'None (0)' | (b) (4), (b) (6) System | 18 Sep 2020 05:03:58 |
| | System | 18 Sep 2020 05:03:58 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:52

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-18T00:03:22', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '9c1428f7-c53b-4b80-b81c-6993760c1882' User entered 'None (0)' | (b) (4), (b) (6) System | 18 Sep 2020 05:03:58 |
| | System | 18 Sep 2020 05:03:58 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:52

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-18T00:03:26', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '9c1428f7-c53b-4b80-b81c-6993760c1882' User entered 'None (0)' | (b) (4), (b) (6) System | 18 Sep 2020 05:03:58 |
| | System | 18 Sep 2020 05:03:58 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:52

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-18T00:03:29', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '9c1428f7-c53b-4b80-b81c-6993760c1882' User entered 'None (0)' | (b) (4), (b) (6) System | 18 Sep 2020 05:03:58 |
| | System | 18 Sep 2020 05:03:58 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:52

CHILLS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-18T00:03:32', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '9c1428f7-c53b-4b80-b81c-6993760c1882' User entered 'None (0)' | (b) (4), (b) (6) System | 18 Sep 2020 05:03:58 |
| | System | 18 Sep 2020 05:03:58 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:52

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) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-18T00:03:38', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '9c1428f7-c53b-4b80-b81c-6993760c1882' User entered 'No (N)' | (b) (4), (b) (6) System | 18 Sep 2020 05:03:58 |
| | System | 18 Sep 2020 05:03:58 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:52

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-18T00:03:52', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '9c1428f7-c53b-4b80-b81c-6993760c1882' User entered '18 Sep 2020 00:03' | (b) (4), (b) (6) System | 18 Sep 2020 05:03:58 |
| | System | 18 Sep 2020 05:03:58 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '17 Sep 2020 12:00' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '18 Sep 2020 11:59' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| Data entry locked. | (b) (4), (b) (6) | |
| | System | 14 Sep 2020 16:17:21 |
| User entered 'Day 5' | System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:52

HEADACHE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-18T21:28:54', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'ff7f6775-5b8e-4803-bcb6-75187e732781' User entered 'None (0)' | (b) (4), (b) (6) System | 19 Sep 2020 02:37:56 |
| | System | 19 Sep 2020 02:37:56 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:52

FATIGUE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-18T21:28:58', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'ff7f6775-5b8e-4803-bcb6-75187e732781' User entered 'None (0)' | (b) (4), (b) (6) System | 19 Sep 2020 02:37:56 |
| | System | 19 Sep 2020 02:37:56 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:52

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-18T21:29:01', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'ff7f6775-5b8e-4803-bcb6-75187e732781' User entered 'None (0)' | (b) (4), (b) (6) System | 19 Sep 2020 02:37:56 |
| | System | 19 Sep 2020 02:37:56 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:52

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-18T21:29:04', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'ff7f6775-5b8e-4803-bcb6-75187e732781' User entered 'None (0)' | (b) (4), (b) (6) System | 19 Sep 2020 02:37:56 |
| | System | 19 Sep 2020 02:37:56 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:52

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-18T21:29:07', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'ff7f6775-5b8e-4803-bcb6-75187e732781' User entered 'None (0)' | (b) (4), (b) (6) System | 19 Sep 2020 02:37:56 |
| | System | 19 Sep 2020 02:37:56 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:52

CHILLS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-18T21:29:10', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'ff7f6775-5b8e-4803-bcb6-75187e732781' User entered 'None (0)' | (b) (4), (b) (6) System | 19 Sep 2020 02:37:56 |
| | System | 19 Sep 2020 02:37:56 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:52

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) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-18T21:29:14', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'ff7f6775-5b8e-4803-bcb6-75187e732781' User entered 'No (N)' | (b) (4), (b) (6) System | 19 Sep 2020 02:37:56 |
| | System | 19 Sep 2020 02:37:56 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:52

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-18T21:29:39', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'ff7f6775-5b8e-4803-bcb6-75187e732781' User entered '18 Sep 2020 21:29' | (b) (4), (b) (6) System | 19 Sep 2020 02:37:56 |
| | System | 19 Sep 2020 02:37:56 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '18 Sep 2020 12:00' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '19 Sep 2020 11:59' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| Data entry locked. | (b) (4), (b) (6) | |
| | System | 14 Sep 2020 16:17:21 |
| User entered 'Day 6' | System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:52

HEADACHE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-19T22:22:59', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'da31b0a5-8497-423b-b8ce-85dcda516800' | (b) (4), (b) (6) System | 20 Sep 2020 03:23:46 |
| User entered 'No interference with activity (1)' | System | 20 Sep 2020 03:23:46 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:52

FATIGUE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-19T22:23:02', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'da31b0a5-8497-423b-b8ce-85dcda516800' User entered 'None (0)' | (b) (4), (b) (6) System | 20 Sep 2020 03:23:46 |
| | System | 20 Sep 2020 03:23:46 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:52

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-19T22:23:06', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'da31b0a5-8497-423b-b8ce-85dcda516800' User entered 'None (0)' | (b) (4), (b) (6) System | 20 Sep 2020 03:23:46 |
| | System | 20 Sep 2020 03:23:46 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:52

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-19T22:23:10', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'da31b0a5-8497-423b-b8ce-85dcda516800' User entered 'None (0)' | (b) (4), (b) (6) System | 20 Sep 2020 03:23:46 |
| | System | 20 Sep 2020 03:23:46 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:52

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-19T22:23:14', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'da31b0a5-8497-423b-b8ce-85dcda516800' User entered 'None (0)' | (b) (4), (b) (6) System | 20 Sep 2020 03:23:46 |
| | System | 20 Sep 2020 03:23:46 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:52

CHILLS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-19T22:23:17', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'da31b0a5-8497-423b-b8ce-85dcda516800' User entered 'None (0)' | (b) (4), (b) (6) System | 20 Sep 2020 03:23:46 |
| | System | 20 Sep 2020 03:23:46 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:52

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) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-19T22:23:26', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'da31b0a5-8497-423b-b8ce-85dcda516800' User entered 'No (N)' | (b) (4), (b) (6) System | 20 Sep 2020 03:23:46 |
| | System | 20 Sep 2020 03:23:46 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:52

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-19T22:23:44', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'da31b0a5-8497-423b-b8ce-85dcda516800' User entered '19 Sep 2020 22:23' | (b) (4), (b) (6) System | 20 Sep 2020 03:23:46 |
| | System | 20 Sep 2020 03:23:46 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '19 Sep 2020 12:00' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '20 Sep 2020 11:59' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| Data entry locked. | (b) (4), (b) (6) | |
| | System | 14 Sep 2020 16:17:21 |
| User entered 'Day 7' | System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:52

HEADACHE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-20T20:59:00', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'a0d6b90b-4fbb-4dee-998a-853e7880db3d' User entered 'None (0)' | (b) (4), (b) (6) System | 21 Sep 2020 01:59:43 |
| | System | 21 Sep 2020 01:59:43 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:52

FATIGUE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-20T20:59:04', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'a0d6b90b-4fbb-4dee-998a-853e7880db3d' User entered 'None (0)' | (b) (4), (b) (6) System | 21 Sep 2020 01:59:43 |
| | System | 21 Sep 2020 01:59:43 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:52

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-20T20:59:07', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'a0d6b90b-4fbb-4dee-998a-853e7880db3d' User entered 'None (0)' | (b) (4), (b) (6) System | 21 Sep 2020 01:59:43 |
| | System | 21 Sep 2020 01:59:43 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:52

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-20T20:59:11', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'a0d6b90b-4fbb-4dee-998a-853e7880db3d' User entered 'None (0)' | (b) (4), (b) (6) System | 21 Sep 2020 01:59:43 |
| | System | 21 Sep 2020 01:59:43 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:52

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-20T20:59:14', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'a0d6b90b-4fbb-4dee-998a-853e7880db3d' User entered 'None (0)' | (b) (4), (b) (6) System | 21 Sep 2020 01:59:43 |
| | System | 21 Sep 2020 01:59:43 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:52

CHILLS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-20T20:59:17', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'a0d6b90b-4fbb-4dee-998a-853e7880db3d' User entered 'None (0)' | (b) (4), (b) (6) System | 21 Sep 2020 01:59:43 |
| | System | 21 Sep 2020 01:59:43 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:52

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) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-20T20:59:27', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'a0d6b90b-4fbb-4dee-998a-853e7880db3d' User entered 'No (N)' | (b) (4), (b) (6) System | 21 Sep 2020 01:59:43 |
| | System | 21 Sep 2020 01:59:43 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:52

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-09-20T20:59:39', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'a0d6b90b-4fbb-4dee-998a-853e7880db3d' User entered '20 Sep 2020 20:59' | (b) (4), (b) (6) System | 21 Sep 2020 01:59:43 |
| | System | 21 Sep 2020 01:59:43 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:52

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '20 Sep 2020 12:00' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:05:52

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| User entered '21 Sep 2020 11:59' | (b) (4), (b) (6) System | 14 Sep 2020 16:17:21 |

US3232056

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 28 Sep 2020 17:48:51 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '21 Sep 2020' | Jerrica Sullivan (b) (4) | 28 Sep 2020 17:48:51 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Contact Made (CONTACT MADE)' | Jerrica Sullivan (b) (4) | 28 Sep 2020 17:48:51 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 28 Sep 2020 17:48:51 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:52

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 28 Sep 2020 17:48:57 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:52

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered 'I' | System | 28 Sep 2020 17:48:57 |

US3232056

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 28 Sep 2020 17:49:06 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '28 Sep 2020' | Jerrica Sullivan (b) (4) | 28 Sep 2020 17:49:06 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Contact Made (CONTACT MADE)' | Jerrica Sullivan (b) (4) | 28 Sep 2020 17:49:06 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 28 Sep 2020 17:49:06 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:52

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 28 Sep 2020 17:49:10 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:52

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered 'I' | (b) (4), (b) (6) | 28 Sep 2020 17:49:10 |
| | System | |

US3232056

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:03:07 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '5 Oct 2020' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:03:07 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Contact Made (CONTACT MADE)' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:03:07 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:03:07 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:52

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:03:11 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:52

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered 'I' | (b) (4), (b) (6) | 05 Oct 2020 22:03:11 |
| | System | |

US3232056

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:52

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 12 Oct 2020 16:15:50 |
| | (b) (4) | |

US3232056

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:52

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '12 Oct 2020' | Adreanna Pou (b) (4) | 12 Oct 2020 16:15:50 |
| | (b) (4) | |

US3232056

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:52

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Clinic (Clinic)' | Adreanna Pou (b) (4) | 12 Oct 2020 16:15:50 |
| | (b) (4) | |

US3232056

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:52

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered 'VISIT3' | System | 12 Oct 2020 16:15:50 |

US3232056

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 12 Oct 2020 16:16:54 |
| | (b) (4) | |

US3232056

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '12 Oct 2020' | Adreanna Pou (b) (4) | 12 Oct 2020 16:16:54 |
| | (b) (4) | |

US3232056

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '09:05' | Adreanna Pou (b) (4) | 12 Oct 2020 16:16:54 |
| | (b) (4) | |

US3232056

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered '12 Oct 2020 09:05' | (b) (4), (b) (6) | 12 Oct 2020 16:16:54 |
| | System | |

US3232056

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '98.6' F | Adreanna Pou (b) (4) | 12 Oct 2020 16:16:54 |
| | (b) (4) | |

US3232056

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Oral (Oral)' | Adreanna Pou (b) (4) | 12 Oct 2020 16:16:54 |
| | (b) (4) | |

US3232056

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 12 Oct 2020 16:16:54 |
| | (b) (4) | |

US3232056

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '72' | Adreanna Pou (b) (4) | 12 Oct 2020 16:16:54 |
| | (b) (4) | |

US3232056

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered 'bpm' | System | 12 Oct 2020 16:16:54 |

US3232056

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '18' | Adreanna Pou (b) (4) | 12 Oct 2020 16:16:54 |
| | (b) (4) | |

US3232056

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered 'breaths/min' | (b) (4), (b) (6) | 12 Oct 2020 16:16:54 |
| | System | |

US3232056

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '115' | Adreanna Pou (b) (4) | 12 Oct 2020 16:16:54 |
| | (b) (4) | |

US3232056

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered 'mmHg' | (b) (4), (b) (6) System | 12 Oct 2020 16:16:54 |

US3232056

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '69' | Adreanna Pou (b) (4) | 12 Oct 2020 16:16:54 |
| | (b) (4) | |

US3232056

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered 'mmHg' | (b) (4), (b) (6) System | 12 Oct 2020 16:16:54 |

US3232056

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |

US3232056

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |

US3232056

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:52

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 12 Oct 2020 16:17:01 |
| | (b) (4) | |

US3232056

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:52

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '12 Oct 2020' | Adreanna Pou (b) (4) | 12 Oct 2020 16:17:01 |
| | (b) (4) | |

US3232056

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:52

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 12 Oct 2020 16:17:27 |
| | (b) (4) | |

US3232056

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:52

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '12 Oct 2020' | Adreanna Pou (b) (4) | 12 Oct 2020 16:17:27 |
| | (b) (4) | |

US3232056

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:52

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered '09:08' | Adreanna Pou (b) (4) | 12 Oct 2020 16:17:27 |
| | (b) (4) | |

US3232056

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:52

Collection date and time (derived)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User entered '12 Oct 2020 09:08' | System | 12 Oct 2020 16:17:27 |

US3232056

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:52

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 18 Feb 2021 15:43:00 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 12 Oct 2020 16:17:32 |
| | (b) (4) | |

US3232056

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:52

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered '1' | (b) (4), (b) (6) | 12 Oct 2020 16:17:32 |
| | System | |

US3232056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 17 Aug 2020 16:23:58 |
| User entered 'Day 64' | System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[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) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-10-19T20:41:48', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '8de9f1c0-06ba-463d-9e74-f30064b62e1c' User entered 'No (N)' | (b) (4), (b) (6) System | 20 Oct 2020 01:42:19 |
| | System | 20 Oct 2020 01:42:19 |

US3232056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

Have you been exposed to someone with 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) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-10-19T20:41:55', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '8de9f1c0-06ba-463d-9e74-f30064b62e1c' User entered 'No (N)' | (b) (4), (b) (6) System | 20 Oct 2020 01:42:19 |
| | System | 20 Oct 2020 01:42:19 |

US3232056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-10-19T20:42:13', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '8de9f1c0-06ba-463d-9e74-f30064b62e1c' User entered '19 Oct 2020 20:42:13' | (b) (4), (b) (6) System | 20 Oct 2020 01:42:19 |
| | System | 20 Oct 2020 01:42:19 |

US3232056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 17 Aug 2020 16:23:58 |
| User entered '17 Oct 2020 00:01' | System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 17 Aug 2020 16:23:58 |
| User entered '21 Oct 2020 23:59' | System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 17 Aug 2020 16:23:58 |
| User entered 'Day 71' | System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-10-26T22:32:01', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '4f233768-07d4-4beb-a49a-204512d8e5e2' | (b) (4), (b) (6) | |
| | System | 27 Oct 2020 03:32:22 |
| User entered 'No (N)' | System | 27 Oct 2020 03:32:22 |

US3232056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

Have you been exposed to someone with 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) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-10-26T22:32:08', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '4f233768-07d4-4beb-a49a-204512d8e5e2' | (b) (4), (b) (6) | |
| | System | 27 Oct 2020 03:32:22 |
| User entered 'No (N)' | System | 27 Oct 2020 03:32:22 |

US3232056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-10-26T22:32:19', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '4f233768-07d4-4beb-a49a-204512d8e5e2' User entered '26 Oct 2020 22:32:19' | (b) (4), (b) (6) System | 27 Oct 2020 03:32:22 |
| | System | 27 Oct 2020 03:32:22 |

US3232056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 17 Aug 2020 16:23:58 |
| User entered '24 Oct 2020 00:01' | System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 17 Aug 2020 16:23:58 |
| User entered '28 Oct 2020 23:59' | System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 17 Aug 2020 16:23:58 |
| User entered 'Day 78' | System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

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) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-11-03T04:37:59', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'fbae0fce-8c1a-428d-8bce-1d6eb995862a' User entered 'No (N)' | (b) (4), (b) (6) System | 03 Nov 2020 10:38:30 |
| | System | 03 Nov 2020 10:38:30 |

US3232056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

Have you been exposed to someone with 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) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-11-03T04:38:15', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'fbae0fce-8c1a-428d-8bce-1d6eb995862a' User entered 'No (N)' | (b) (4), (b) (6) System | 03 Nov 2020 10:38:30 |
| | System | 03 Nov 2020 10:38:30 |

US3232056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-11-03T04:38:27', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'fbae0fce-8c1a-428d-8bce-1d6eb995862a' User entered '03 Nov 2020 04:38:27' | (b) (4), (b) (6) System | 03 Nov 2020 10:38:30 |
| | System | 03 Nov 2020 10:38:30 |

US3232056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 17 Aug 2020 16:23:58 |
| User entered '31 Oct 2020 00:01' | System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 17 Aug 2020 16:23:58 |
| User entered '04 Nov 2020 23:59' | System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 17 Aug 2020 16:23:58 |
| User entered 'Day 92' | System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[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) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-11-17T17:59:46', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '67eefa40-25bc-4064-9eda-521f1e1765ea' | (b) (4), (b) (6) | |
| | System | 18 Nov 2020 00:00:08 |
| User entered 'No (N)' | System | 18 Nov 2020 00:00:08 |

US3232056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

Have you been exposed to someone with 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) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-11-17T17:59:52', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '67eefa40-25bc-4064-9eda-521f1e1765ea' | (b) (4), (b) (6) | |
| | System | 18 Nov 2020 00:00:08 |
| User entered 'No (N)' | System | 18 Nov 2020 00:00:08 |

US3232056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-11-17T18:00:05', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '67eefa40-25bc-4064-9eda-521f1e1765ea' User entered '17 Nov 2020 18:00:05' | (b) (4), (b) (6) System | 18 Nov 2020 00:00:08 |
| | System | 18 Nov 2020 00:00:08 |

US3232056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 17 Aug 2020 16:23:58 |
| User entered '14 Nov 2020 00:01' | System | 17 Aug 2020 16:23:58 |

US3232056

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:20:33 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 17 Aug 2020 16:23:58 |
| User entered '18 Nov 2020 23:59' | System | 17 Aug 2020 16:23:58 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 96' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '18 Nov 2020 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '22 Nov 2020 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 103' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-11-25T11:59:56', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '3923370b-3b13-40b1-b12b-8be15eb78069' | System | 25 Nov 2020 18:00:10 |
| User entered 'No (N)' | System | 25 Nov 2020 18:00:10 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-11-25T12:00:00', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '3923370b-3b13-40b1-b12b-8be15eb78069' | System | 25 Nov 2020 18:00:10 |
| User entered 'No (N)' | System | 25 Nov 2020 18:00:10 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-11-25T12:00:06', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '3923370b-3b13-40b1-b12b-8be15eb78069' | System | 25 Nov 2020 18:00:10 |
| User entered '25 Nov 2020 12:00:06' | System | 25 Nov 2020 18:00:10 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '25 Nov 2020 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '29 Nov 2020 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-12-02T00:01:53', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '3d36e7a5-6828-4400-9884-a72ebb4e1174' | System | 02 Dec 2020 06:02:10 |
| User entered 'No (N)' | System | 02 Dec 2020 06:02:10 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-12-02T00:02:02', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '3d36e7a5-6828-4400-9884-a72ebb4e1174' | System | 02 Dec 2020 06:02:10 |
| User entered 'No (N)' | System | 02 Dec 2020 06:02:10 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-12-02T00:02:06', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '3d36e7a5-6828-4400-9884-a72ebb4e1174' | System | 02 Dec 2020 06:02:10 |
| User entered '02 Dec 2020 00:02:06' | System | 02 Dec 2020 06:02:10 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '02 Dec 2020 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '06 Dec 2020 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-12-09T00:01:58', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '8de52aad-00c2-4703-864c-ace29609d477' | System | 09 Dec 2020 06:02:38 |
| User entered 'No (N)' | System | 09 Dec 2020 06:02:38 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-12-09T00:02:12', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '8de52aad-00c2-4703-864c-ace29609d477' | System | 09 Dec 2020 06:02:38 |
| User entered 'No (N)' | System | 09 Dec 2020 06:02:38 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-12-09T00:02:32', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '8de52aad-00c2-4703-864c-ace29609d477' | System | 09 Dec 2020 06:02:38 |
| User entered '09 Dec 2020 00:02:32' | System | 09 Dec 2020 06:02:38 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '09 Dec 2020 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '13 Dec 2020 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-12-16T00:31:17', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'c3d96c49-6d36-4853-b15d-3fe98c201144' | System | 16 Dec 2020 06:31:39 |
| User entered 'No (N)' | System | 16 Dec 2020 06:31:39 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-12-16T00:31:27', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'c3d96c49-6d36-4853-b15d-3fe98c201144' | System | 16 Dec 2020 06:31:39 |
| User entered 'No (N)' | System | 16 Dec 2020 06:31:39 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-12-16T00:31:35', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'c3d96c49-6d36-4853-b15d-3fe98c201144' | System | 16 Dec 2020 06:31:39 |
| User entered '16 Dec 2020 00:31:35' | System | 16 Dec 2020 06:31:39 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '16 Dec 2020 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '20 Dec 2020 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-12-23T06:50:28', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '7ec4b10d-7f81-4d30-b688-75e4c0e4b015' User entered 'No (N)' | System | 23 Dec 2020 11:50:43 |
| | System | 23 Dec 2020 11:50:43 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-12-23T06:50:33', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '7ec4b10d-7f81-4d30-b688-75e4c0e4b015' User entered 'No (N)' | System | 23 Dec 2020 11:50:43 |
| | System | 23 Dec 2020 11:50:43 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-12-23T06:50:39', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '7ec4b10d-7f81-4d30-b688-75e4c0e4b015' User entered '23 Dec 2020 06:50:39' | System | 23 Dec 2020 11:50:43 |
| | System | 23 Dec 2020 11:50:43 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '23 Dec 2020 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '27 Dec 2020 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-12-30T00:02:33', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '461d8ed4-7d7b-446b-8ab3-ae627f9da81a' User entered 'No (N)' | System | 30 Dec 2020 05:02:58 |
| | System | 30 Dec 2020 05:02:58 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-12-30T00:02:41', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '461d8ed4-7d7b-446b-8ab3-ae627f9da81a' User entered 'No (N)' | System | 30 Dec 2020 05:02:58 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B6F55C8B-79B4-4BB4-9885-F127C40ACD5B)', Time: '2020-12-30T00:02:55', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '461d8ed4-7d7b-446b-8ab3-ae627f9da81a' User entered '30 Dec 2020 00:02:55' | System | 30 Dec 2020 05:02:58 |
| | System | 30 Dec 2020 05:02:58 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '30 Dec 2020 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '03 Jan 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-01-08T14:56:18', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '1c333ef6-4ccb-40fa-9d2c-a03284fec295' | System | 08 Jan 2021 20:58:05 |
| User entered 'Yes (Y)' | System | 08 Jan 2021 20:58:05 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-01-08T14:56:25', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '1c333ef6-4ccb-40fa-9d2c-a03284fec295' | System | 08 Jan 2021 20:58:05 |
| User entered 'Yes (Y)' | System | 08 Jan 2021 20:58:05 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-01-08T14:56:34', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '1c333ef6-4ccb-40fa-9d2c-a03284fec295' | System | 08 Jan 2021 20:58:05 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 08 Jan 2021 20:58:05 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-01-08T14:56:41', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '1c333ef6-4ccb-40fa-9d2c-a03284fec295' | System | 08 Jan 2021 20:58:05 |
| User entered 'Yes (Y)' | System | 08 Jan 2021 20:58:05 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

Fever (Temperature \geq 100.4°F/38°C)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-01-08T14:57:06', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '1c333ef6-4ccb-40fa-9d2c-a03284fec295' | System | 08 Jan 2021 20:58:05 |
| User entered '0' | System | 08 Jan 2021 20:58:05 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-01-08T14:57:06', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '1c333ef6-4ccb-40fa-9d2c-a03284fec295' | System | 08 Jan 2021 20:58:05 |
| User entered '0' | System | 08 Jan 2021 20:58:05 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-01-08T14:57:06', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '1c333ef6-4ccb-40fa-9d2c-a03284fec295' | System | 08 Jan 2021 20:58:05 |
| User entered '1' | System | 08 Jan 2021 20:58:05 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Shortness of breath](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-01-08T14:57:06', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '1c333ef6-4ccb-40fa-9d2c-a03284fec295' | System | 08 Jan 2021 20:58:05 |
| User entered '0' | System | 08 Jan 2021 20:58:05 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Difficulty breathing](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-01-08T14:57:06', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '1c333ef6-4ccb-40fa-9d2c-a03284fec295' | System | 08 Jan 2021 20:58:05 |
| User entered '0' | System | 08 Jan 2021 20:58:05 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-01-08T14:57:06', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '1c333ef6-4ccb-40fa-9d2c-a03284fec295' | System | 08 Jan 2021 20:58:05 |
| User entered '0' | System | 08 Jan 2021 20:58:05 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Muscle aches](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-01-08T14:57:06', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '1c333ef6-4ccb-40fa-9d2c-a03284fec295' | System | 08 Jan 2021 20:58:05 |
| User entered '1' | System | 08 Jan 2021 20:58:05 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Body aches](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-01-08T14:57:06', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '1c333ef6-4ccb-40fa-9d2c-a03284fec295' | System | 08 Jan 2021 20:58:05 |
| User entered '0' | System | 08 Jan 2021 20:58:05 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-01-08T14:57:06', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '1c333ef6-4ccb-40fa-9d2c-a03284fec295' | System | 08 Jan 2021 20:58:05 |
| User entered '1' | System | 08 Jan 2021 20:58:05 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[New loss of taste](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-01-08T14:57:06', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '1c333ef6-4ccb-40fa-9d2c-a03284fec295' | System | 08 Jan 2021 20:58:05 |
| User entered '0' | System | 08 Jan 2021 20:58:05 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[New loss of smell](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-01-08T14:57:06', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '1c333ef6-4ccb-40fa-9d2c-a03284fec295' | System | 08 Jan 2021 20:58:05 |
| User entered '0' | System | 08 Jan 2021 20:58:05 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Sore throat](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-01-08T14:57:06', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '1c333ef6-4ccb-40fa-9d2c-a03284fec295' | System | 08 Jan 2021 20:58:05 |
| User entered '0' | System | 08 Jan 2021 20:58:05 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-01-08T14:57:06', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '1c333ef6-4ccb-40fa-9d2c-a03284fec295' | System | 08 Jan 2021 20:58:05 |
| User entered '0' | System | 08 Jan 2021 20:58:05 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Runny nose](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-01-08T14:57:06', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '1c333ef6-4ccb-40fa-9d2c-a03284fec295' | System | 08 Jan 2021 20:58:05 |
| User entered '0' | System | 08 Jan 2021 20:58:05 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-01-08T14:57:06', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '1c333ef6-4ccb-40fa-9d2c-a03284fec295' | System | 08 Jan 2021 20:58:05 |
| User entered '0' | System | 08 Jan 2021 20:58:05 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-01-08T14:57:06', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '1c333ef6-4ccb-40fa-9d2c-a03284fec295' | System | 08 Jan 2021 20:58:05 |
| User entered '0' | System | 08 Jan 2021 20:58:05 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-01-08T14:57:06', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '1c333ef6-4ccb-40fa-9d2c-a03284fec295' | System | 08 Jan 2021 20:58:05 |
| User entered '0' | System | 08 Jan 2021 20:58:05 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-01-08T14:57:13', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '1c333ef6-4ccb-40fa-9d2c-a03284fec295' | System | 08 Jan 2021 20:58:05 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 08 Jan 2021 20:58:05 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-01-08T14:57:25', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '1c333ef6-4ccb-40fa-9d2c-a03284fec295' | System | 08 Jan 2021 20:58:05 |
| User entered 'Yes (Y)' | System | 08 Jan 2021 20:58:05 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-01-08T14:57:32', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '1c333ef6-4ccb-40fa-9d2c-a03284fec295' | System | 08 Jan 2021 20:58:05 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 08 Jan 2021 20:58:05 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-01-08T14:57:54', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '1c333ef6-4ccb-40fa-9d2c-a03284fec295' User entered '08 Jan 2021 14:57:54' | System | 08 Jan 2021 20:58:05 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '06 Jan 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '10 Jan 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-01-13T09:44:49', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '03843fc7-34b3-4466-a838-627e365c0fa5' | System | 13 Jan 2021 15:45:43 |
| User entered 'No (N)' | System | 13 Jan 2021 15:45:43 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-01-13T09:45:28', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '03843fc7-34b3-4466-a838-627e365c0fa5' User entered 'No (N)' | System | 13 Jan 2021 15:45:43 |
| | System | 13 Jan 2021 15:45:43 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-01-13T09:45:38', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '03843fc7-34b3-4466-a838-627e365c0fa5' User entered '13 Jan 2021 09:45:38' | System | 13 Jan 2021 15:45:43 |
| | System | 13 Jan 2021 15:45:43 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '13 Jan 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '17 Jan 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-01-20T06:45:52', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '32eb6fea-1f9f-4821-9d48-641569a8a915' | System | 20 Jan 2021 12:47:24 |
| User entered 'Yes (Y)' | System | 20 Jan 2021 12:47:24 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-01-20T06:46:04', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '32eb6fea-1f9f-4821-9d48-641569a8a915' | System | 20 Jan 2021 12:47:24 |
| User entered 'Yes (Y)' | System | 20 Jan 2021 12:47:24 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-01-20T06:46:16', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '32eb6fea-1f9f-4821-9d48-641569a8a915' | System | 20 Jan 2021 12:47:24 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 20 Jan 2021 12:47:24 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-01-20T06:46:27', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '32eb6fea-1f9f-4821-9d48-641569a8a915' | System | 20 Jan 2021 12:47:24 |
| User entered 'No (N)' | System | 20 Jan 2021 12:47:24 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-01-20T06:46:36', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '32eb6fea-1f9f-4821-9d48-641569a8a915' | System | 20 Jan 2021 12:47:24 |
| User entered 'Yes (Y)' | System | 20 Jan 2021 12:47:24 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-01-20T06:46:44', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '32eb6fea-1f9f-4821-9d48-641569a8a915' | System | 20 Jan 2021 12:47:24 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 20 Jan 2021 12:47:24 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-01-20T06:47:13', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '32eb6fea-1f9f-4821-9d48-641569a8a915' | System | 20 Jan 2021 12:47:24 |
| User entered '20 Jan 2021 06:47:13' | System | 20 Jan 2021 12:47:24 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '20 Jan 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '24 Jan 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-01-27T00:27:26', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '32032d97-8158-43da-b176-9e9f5bedf706' | System | 27 Jan 2021 06:27:40 |
| User entered 'No (N)' | System | 27 Jan 2021 06:27:40 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-01-27T00:27:30', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '32032d97-8158-43da-b176-9e9f5bedf706' | System | 27 Jan 2021 06:27:40 |
| User entered 'No (N)' | System | 27 Jan 2021 06:27:40 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-01-27T00:27:37', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '32032d97-8158-43da-b176-9e9f5bedf706' User entered '27 Jan 2021 00:27:37' | System | 27 Jan 2021 06:27:40 |
| | System | 27 Jan 2021 06:27:40 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '27 Jan 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '31 Jan 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-02-03T00:01:37', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '232201fa-10bf-4818-bb48-1d6d47297d7e' User entered 'No (N)' | System | 03 Feb 2021 06:01:56 |
| | System | 03 Feb 2021 06:01:56 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-02-03T00:01:40', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '232201fa-10bf-4818-bb48-1d6d47297d7e' | System | 03 Feb 2021 06:01:56 |
| User entered 'No (N)' | System | 03 Feb 2021 06:01:56 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-02-03T00:01:52', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '232201fa-10bf-4818-bb48-1d6d47297d7e' User entered '03 Feb 2021 00:01:52' | System | 03 Feb 2021 06:01:56 |
| | System | 03 Feb 2021 06:01:56 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '03 Feb 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '07 Feb 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-02-11T08:37:38', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'fc7a671f-93fe-4c6a-8c7f-38882019c30b' User entered 'No (N)' | System | 11 Feb 2021 14:37:51 |
| | System | 11 Feb 2021 14:37:51 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-02-11T08:37:44', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'fc7a671f-93fe-4c6a-8c7f-38882019c30b' User entered 'No (N)' | System | 11 Feb 2021 14:37:51 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-02-11T08:37:49', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'fc7a671f-93fe-4c6a-8c7f-38882019c30b' | System | 11 Feb 2021 14:37:51 |
| User entered '11 Feb 2021 08:37:49' | System | 11 Feb 2021 14:37:51 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '10 Feb 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '14 Feb 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-02-17T00:01:23', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '079f2803-94b9-402f-bc1c-dacb9f6662f3' | System | 17 Feb 2021 06:01:48 |
| User entered 'No (N)' | System | 17 Feb 2021 06:01:48 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-02-17T00:01:29', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '079f2803-94b9-402f-bc1c-dacb9f6662f3' | System | 17 Feb 2021 06:01:48 |
| User entered 'No (N)' | System | 17 Feb 2021 06:01:48 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-02-17T00:01:39', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '079f2803-94b9-402f-bc1c-dacb9f6662f3' | System | 17 Feb 2021 06:01:48 |
| User entered '17 Feb 2021 00:01:39' | System | 17 Feb 2021 06:01:48 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '17 Feb 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '21 Feb 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-02-24T00:01:40-06:00', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '4f3136af-5d25-4c4c-b276-4a141b2bffc3' | System | 24 Feb 2021 06:01:55 |
| User entered 'No (N)' | System | 24 Feb 2021 06:01:55 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-02-24T00:01:46-06:00', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '4f3136af-5d25-4c4c-b276-4a141b2bffc3' | System | 24 Feb 2021 06:01:55 |
| User entered 'No (N)' | System | 24 Feb 2021 06:01:55 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-02-24T00:01:53-06:00', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '4f3136af-5d25-4c4c-b276-4a141b2bffc3' | System | 24 Feb 2021 06:01:55 |
| User entered '24 Feb 2021 06:01:53' | System | 24 Feb 2021 06:01:55 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '24 Feb 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '28 Feb 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-03-03T11:45:50-06:00', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '1d6a6b37-0ba3-49e2-b137-146f701583bb' | System | 03 Mar 2021 17:46:50 |
| User entered 'No (N)' | System | 03 Mar 2021 17:46:50 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-03-03T11:45:58-06:00', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '1d6a6b37-0ba3-49e2-b137-146f701583bb' | System | 03 Mar 2021 17:46:50 |
| User entered 'No (N)' | System | 03 Mar 2021 17:46:50 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-03-03T11:46:07-06:00', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '1d6a6b37-0ba3-49e2-b137-146f701583bb' | System | 03 Mar 2021 17:46:50 |
| User entered '03 Mar 2021 11:46:07' | System | 03 Mar 2021 17:46:50 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '03 Mar 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '07 Mar 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-03-10T00:02:42-06:00', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'd01a18d4-9026-478a-a6b0-5e719776845d' | System | 10 Mar 2021 06:03:36 |
| User entered 'Yes (Y)' | System | 10 Mar 2021 06:03:36 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-03-10T00:02:48-06:00', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'd01a18d4-9026-478a-a6b0-5e719776845d' | System | 10 Mar 2021 06:03:36 |
| User entered 'No (N)' | System | 10 Mar 2021 06:03:36 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-03-10T00:02:55-06:00', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'd01a18d4-9026-478a-a6b0-5e719776845d' | System | 10 Mar 2021 06:03:36 |
| User entered 'No (N)' | System | 10 Mar 2021 06:03:36 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-03-10T00:03:04-06:00', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'd01a18d4-9026-478a-a6b0-5e719776845d' | System | 10 Mar 2021 06:03:36 |
| User entered 'No (N)' | System | 10 Mar 2021 06:03:36 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-03-10T00:03:29-06:00', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'd01a18d4-9026-478a-a6b0-5e719776845d' | System | 10 Mar 2021 06:03:36 |
| User entered '10 Mar 2021 00:03:29' | System | 10 Mar 2021 06:03:36 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '10 Mar 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '14 Mar 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-03-17T00:14:02-05:00', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '9680ad19-fe1d-406c-9c93-ce53e8efa233' | System | 17 Mar 2021 05:14:23 |
| User entered 'No (N)' | System | 17 Mar 2021 05:14:23 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-03-17T00:14:14-05:00', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '9680ad19-fe1d-406c-9c93-ce53e8efa233' | System | 17 Mar 2021 05:14:23 |
| User entered 'No (N)' | System | 17 Mar 2021 05:14:23 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-03-17T00:14:21-05:00', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '9680ad19-fe1d-406c-9c93-ce53e8efa233' | System | 17 Mar 2021 05:14:23 |
| User entered '17 Mar 2021 00:14:21' | System | 17 Mar 2021 05:14:23 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '17 Mar 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '21 Mar 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-03-24T00:21:00-05:00', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '2fc0c197-a8a0-428c-9c8b-1a0fd443228d' | System | 24 Mar 2021 05:21:24 |
| User entered 'No (N)' | System | 24 Mar 2021 05:21:24 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-03-24T00:21:05-05:00', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '2fc0c197-a8a0-428c-9c8b-1a0fd443228d' | System | 24 Mar 2021 05:21:24 |
| User entered 'No (N)' | System | 24 Mar 2021 05:21:24 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-03-24T00:21:22-05:00', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '2fc0c197-a8a0-428c-9c8b-1a0fd443228d' User entered '24 Mar 2021 00:21:22' | System | 24 Mar 2021 05:21:24 |
| | System | 24 Mar 2021 05:21:24 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '24 Mar 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '28 Mar 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-03-31T00:02:39-05:00', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '36b9eac0-2518-4776-9250-e3e36e04fc5d' User entered 'No (N)' | System | 31 Mar 2021 05:03:11 |
| | System | 31 Mar 2021 05:03:11 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-03-31T00:02:47-05:00', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '36b9eac0-2518-4776-9250-e3e36e04fc5d' User entered 'No (N)' | System | 31 Mar 2021 05:03:11 |
| | System | 31 Mar 2021 05:03:11 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-03-31T00:03:01-05:00', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '36b9eac0-2518-4776-9250-e3e36e04fc5d' User entered '31 Mar 2021 00:03:01' | System | 31 Mar 2021 05:03:11 |
| | System | 31 Mar 2021 05:03:11 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '31 Mar 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '04 Apr 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-04-07T03:46:04-05:00', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '2e8561b7-7efc-4c0b-82de-0b2ef87ed4c4' | System | 07 Apr 2021 08:46:42 |
| User entered 'No (N)' | System | 07 Apr 2021 08:46:42 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-04-07T03:46:18-05:00', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '2e8561b7-7efc-4c0b-82de-0b2ef87ed4c4' | System | 07 Apr 2021 08:46:42 |
| User entered 'No (N)' | System | 07 Apr 2021 08:46:42 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-04-07T03:46:40-05:00', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '2e8561b7-7efc-4c0b-82de-0b2ef87ed4c4' | System | 07 Apr 2021 08:46:42 |
| User entered '07 Apr 2021 03:46:40' | System | 07 Apr 2021 08:46:42 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '07 Apr 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '11 Apr 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-04-16T13:11:16-05:00', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '5e848b6c-12f7-43b6-a268-bb6f301e0632' | System | 16 Apr 2021 18:11:32 |
| User entered 'No (N)' | System | 16 Apr 2021 18:11:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-04-16T13:11:19-05:00', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '5e848b6c-12f7-43b6-a268-bb6f301e0632' | System | 16 Apr 2021 18:11:32 |
| User entered 'No (N)' | System | 16 Apr 2021 18:11:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-04-16T13:11:25-05:00', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '5e848b6c-12f7-43b6-a268-bb6f301e0632' | System | 16 Apr 2021 18:11:32 |
| User entered '16 Apr 2021 13:11:25' | System | 16 Apr 2021 18:11:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '14 Apr 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '18 Apr 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-04-21T02:33:05-05:00', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '26140d09-d4fa-44b8-b0e7-62c1320537bb' User entered 'No (N)' | System | 27 Apr 2021 01:43:56 |
| | System | 27 Apr 2021 01:43:56 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-04-21T02:33:12-05:00', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '26140d09-d4fa-44b8-b0e7-62c1320537bb' User entered 'No (N)' | System | 27 Apr 2021 01:43:56 |
| | System | 27 Apr 2021 01:43:56 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-04-21T02:33:22-05:00', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '26140d09-d4fa-44b8-b0e7-62c1320537bb' User entered '21 Apr 2021 02:33:22' | System | 27 Apr 2021 01:43:56 |
| | System | 27 Apr 2021 01:43:56 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '21 Apr 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '25 Apr 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-04-29T01:21:51-05:00', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'ea86d5d8-5d12-4c6f-8da0-9e302e3202fc' User entered 'No (N)' | System | 29 Apr 2021 06:22:08 |
| | System | 29 Apr 2021 06:22:08 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-04-29T01:21:55-05:00', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'ea86d5d8-5d12-4c6f-8da0-9e302e3202fc' User entered 'No (N)' | System | 29 Apr 2021 06:22:08 |
| | System | 29 Apr 2021 06:22:08 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-04-29T01:22:06-05:00', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: 'ea86d5d8-5d12-4c6f-8da0-9e302e3202fc' User entered '29 Apr 2021 01:22:06' | System | 29 Apr 2021 06:22:08 |
| | System | 29 Apr 2021 06:22:08 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '28 Apr 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '02 May 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '05 May 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '09 May 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '12 May 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '16 May 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '19 May 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '23 May 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '26 May 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '30 May 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '02 Jun 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '06 Jun 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '09 Jun 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '13 Jun 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '16 Jun 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '20 Jun 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '23 Jun 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '27 Jun 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '30 Jun 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '04 Jul 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '07 Jul 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '11 Jul 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '14 Jul 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '18 Jul 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '21 Jul 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '25 Jul 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '28 Jul 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '01 Aug 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '04 Aug 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '08 Aug 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '11 Aug 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '15 Aug 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '18 Aug 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '22 Aug 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '25 Aug 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '29 Aug 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '01 Sep 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '05 Sep 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '08 Sep 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '12 Sep 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '15 Sep 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '19 Sep 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '22 Sep 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '26 Sep 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '29 Sep 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '03 Oct 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '06 Oct 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '10 Oct 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '13 Oct 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '17 Oct 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '20 Oct 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '24 Oct 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '27 Oct 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '31 Oct 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '03 Nov 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '07 Nov 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '10 Nov 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '14 Nov 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '17 Nov 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '21 Nov 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '24 Nov 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '28 Nov 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '01 Dec 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '05 Dec 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '08 Dec 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '12 Dec 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '15 Dec 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '19 Dec 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '22 Dec 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '26 Dec 2021 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '29 Dec 2021 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '02 Jan 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '05 Jan 2022 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '09 Jan 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '12 Jan 2022 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '16 Jan 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '19 Jan 2022 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '23 Jan 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '26 Jan 2022 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '30 Jan 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '02 Feb 2022 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '06 Feb 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '09 Feb 2022 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '13 Feb 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '16 Feb 2022 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '20 Feb 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '23 Feb 2022 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '27 Feb 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '02 Mar 2022 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '06 Mar 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '09 Mar 2022 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '13 Mar 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '16 Mar 2022 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '20 Mar 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '23 Mar 2022 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '27 Mar 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '30 Mar 2022 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '03 Apr 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '06 Apr 2022 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '10 Apr 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '13 Apr 2022 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '17 Apr 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '20 Apr 2022 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '24 Apr 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '27 Apr 2022 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '01 May 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '04 May 2022 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '08 May 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '11 May 2022 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '15 May 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '18 May 2022 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '22 May 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '25 May 2022 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '29 May 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '01 Jun 2022 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '05 Jun 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '08 Jun 2022 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '12 Jun 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '15 Jun 2022 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '19 Jun 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '22 Jun 2022 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '26 Jun 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '29 Jun 2022 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '03 Jul 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '06 Jul 2022 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '10 Jul 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '13 Jul 2022 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '17 Jul 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '20 Jul 2022 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '24 Jul 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '27 Jul 2022 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '31 Jul 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '03 Aug 2022 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '07 Aug 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '10 Aug 2022 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '14 Aug 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '17 Aug 2022 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '21 Aug 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '24 Aug 2022 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '28 Aug 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '31 Aug 2022 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '04 Sep 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '07 Sep 2022 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '11 Sep 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '14 Sep 2022 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '18 Sep 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '21 Sep 2022 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '25 Sep 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '28 Sep 2022 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '02 Oct 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '05 Oct 2022 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '09 Oct 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '12 Oct 2022 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '16 Oct 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '19 Oct 2022 00:01' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:52

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 09:03:32 |
| Amendment Manager: User entered '23 Oct 2022 23:59' | System | 19 Nov 2020 09:03:32 |

US3232056

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:05:52

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:46:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-03-01T21:44:19-06:00', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '1273b5a0-7b17-4b4f-8e99-bb29833b0a0b' | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 02 Mar 2021 03:44:36 |

US3232056

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:05:52

[Date & Time of Submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:46:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0981F2B-2026-4D42-86B5-39FB9865FA57)', Time: '2021-03-01T21:44:31-06:00', User OID: 'PatientReportedOutcome (US3232056)', ODM File OID: '1273b5a0-7b17-4b4f-8e99-bb29833b0a0b' User entered '01 Mar 2021 21:44:31' | (b) (4), (b) (6) System | 02 Mar 2021 03:44:36 |
| | System | 02 Mar 2021 03:44:36 |

US3232056

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 05 Mar 2021 16:40:17 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 09 Nov 2020 19:49:15 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 05 Mar 2021 16:40:17 |
| | (b) (4) | |
| User entered '09 Nov 2020' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) | 14 Dec 2020 19:46:04 |
| | (b) (4) | |
| User entered '9 Nov 2020' | Jerrica Sullivan (b) (4) | 09 Nov 2020 19:49:15 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 05 Mar 2021 16:40:17 |
| | (b) (4) | |
| User entered 'Contact Made (CONTACT MADE)' | Jerrica Sullivan (b) (4) | 09 Nov 2020 19:49:15 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 05 Mar 2021 16:40:17 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 09 Nov 2020 19:49:15 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:52

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 05 Mar 2021 16:36:48 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 09 Nov 2020 19:49:07 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:52

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 15:58:59 |
| User entered 'I' | (b) (4), (b) (6) | 09 Nov 2020 19:49:07 |
| | System | |

US3232056

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 14 Dec 2020 19:46:12 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '14 Dec 2020' | Jerrica Sullivan (b) (4) | 14 Dec 2020 19:46:12 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Contact Made (CONTACT MADE)' | Jerrica Sullivan (b) (4) | 14 Dec 2020 19:46:12 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 14 Dec 2020 19:46:12 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:52

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 14 Dec 2020 19:46:16 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:52

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| User entered 'I' | (b) (4), (b) (6) System | 14 Dec 2020 19:46:16 |

US3232056

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 13 Jan 2021 14:47:01 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '12 Jan 2021' | Jerrica Sullivan (b) (4) | 13 Jan 2021 14:47:01 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Contact Made (CONTACT MADE)' | Jerrica Sullivan (b) (4) | 13 Jan 2021 14:47:01 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 13 Jan 2021 14:47:01 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:52

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 13 Jan 2021 14:48:24 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:52

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| User entered '1' | (b) (4), (b) (6) System | 13 Jan 2021 14:48:24 |

US3232056

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 12 Feb 2021 18:58:38 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '12 Feb 2021' | Jerrica Sullivan (b) (4) | 12 Feb 2021 18:58:38 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Contact Made (CONTACT MADE)' | Jerrica Sullivan (b) (4) | 12 Feb 2021 18:58:38 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 12 Feb 2021 18:58:38 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:52

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 12 Feb 2021 18:58:46 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:52

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| User entered '1' | (b) (4), (b) (6) System | 12 Feb 2021 18:58:46 |

US3232056

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:52

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:42:12 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 24 Mar 2021 16:40:11 |
| | (b) (4) | |

US3232056

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:52

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:42:12 |
| | (b) (4) | |
| User entered '24 Mar 2021' | Adreanna Pou (b) (4) | 24 Mar 2021 16:40:11 |
| | (b) (4) | |

US3232056

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:52

Was visit performed at the participant's home or at the clinic?

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:42:12 |
| | (b) (4) | |
| User entered 'Clinic (Clinic)' | Adreanna Pou (b) (4) | 24 Mar 2021 16:40:11 |
| | (b) (4) | |

US3232056

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:52

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| User entered 'VISIT4' | (b) (4), (b) (6) System | 24 Mar 2021 16:40:11 |

US3232056

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:42:12 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 30 Mar 2021 17:17:31 |
| | (b) (4) | |

US3232056

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:42:12 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 30 Mar 2021 17:17:31 |
| | (b) (4) | |

US3232056

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:42:12 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 30 Mar 2021 17:17:31 |
| | (b) (4) | |

US3232056

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| User entered empty. | (b) (4), (b) (6) System | 30 Mar 2021 17:17:31 |

US3232056

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:42:12 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 30 Mar 2021 17:17:31 |
| | (b) (4) | |

US3232056

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:42:12 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 30 Mar 2021 17:17:31 |
| | (b) (4) | |

US3232056

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:42:12 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 30 Mar 2021 17:17:31 |
| | (b) (4) | |

US3232056

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:42:12 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 30 Mar 2021 17:17:31 |
| | (b) (4) | |

US3232056

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| User entered empty. | (b) (4), (b) (6) System | 30 Mar 2021 17:17:31 |

US3232056

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:42:12 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 30 Mar 2021 17:17:31 |
| | (b) (4) | |

US3232056

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| User entered empty. | (b) (4), (b) (6) System | 30 Mar 2021 17:17:31 |

US3232056

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:42:12 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 30 Mar 2021 17:17:31 |
| | (b) (4) | |

US3232056

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| User entered empty. | (b) (4), (b) (6) System | 30 Mar 2021 17:17:31 |

US3232056

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:42:12 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 30 Mar 2021 17:17:31 |
| | (b) (4) | |

US3232056

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| User entered empty. | (b) (4), (b) (6) System | 30 Mar 2021 17:17:31 |

US3232056

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |

US3232056

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |

US3232056

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:52

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:42:12 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 24 Mar 2021 16:40:19 |
| | (b) (4) | |

US3232056

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:52

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:42:12 |
| | (b) (4) | |
| User entered '24 Mar 2021' | Adreanna Pou (b) (4) | 24 Mar 2021 16:40:19 |
| | (b) (4) | |

US3232056

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:52

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:42:12 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 24 Mar 2021 16:40:32 |
| | (b) (4) | |

US3232056

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:52

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:42:12 |
| | (b) (4) | |
| User entered '24 Mar 2021' | Adreanna Pou (b) (4) | 24 Mar 2021 16:40:32 |
| | (b) (4) | |

US3232056

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:52

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:42:12 |
| | (b) (4) | |
| User entered '09:40' | Adreanna Pou (b) (4) | 24 Mar 2021 16:40:32 |
| | (b) (4) | |

US3232056

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:52

Collection date and time (derived)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| User entered '24 Mar 2021 09:40' | (b) (4), (b) (6) System | 24 Mar 2021 16:40:32 |

US3232056

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:52

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:42:12 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 24 Mar 2021 16:40:37 |
| | (b) (4) | |

US3232056

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:52

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:21:56 |
| User entered 'I' | (b) (4), (b) (6) System | 24 Mar 2021 16:40:37 |

US3232056

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 16 Apr 2021 16:00:21 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 12 Apr 2021 14:31:08 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 16 Apr 2021 16:00:21 |
| | (b) (4) | |
| User entered '12 Apr 2021' | Adreanna Pou (b) (4) | 12 Apr 2021 14:31:08 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 16 Apr 2021 16:00:21 |
| | (b) (4) | |
| User entered 'Contact Made (CONTACT MADE)' | Adreanna Pou (b) (4) | 12 Apr 2021 14:31:08 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 16 Apr 2021 16:00:21 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 12 Apr 2021 14:31:08 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:52

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 16 Apr 2021 16:00:21 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 12 Apr 2021 14:31:14 |
| | (b) (4) | |

US3232056

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:52

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 12 Apr 2021 14:31:14 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:05:52

[Date of Contact](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:42 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:44:59 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '08 Jan 2021' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:48:13 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:05:52

[Time of Contact](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:42 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:44:59 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '11:59' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:48:13 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:05:52

[Date and Time of Contact \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:42 |
| User entered '08 Jan 2021 11:59' | (b) (4), (b) (6) System | 08 Jan 2021 21:48:13 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:05:52

[Type of Contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:42 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:44:59 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:48:13 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:05:52

[Has the subject reported symptoms of SARS-COV-2?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:42 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:44:59 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Yes (Y)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:48:13 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Day 1 (Day 1)' | Jerrica Sullivan (b) (4) | 08 Jan 2021 21:51:06 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '02 Jan 2021' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:51:06 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '0' reason for change: Data Entry Error | (b) (4) Jerrica Sullivan (b) (4) | 11 Jan 2021 17:39:17 |
| User entered '1' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:51:06 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) Jerrica Sullivan (b) (4) | 11 Jan 2021 17:39:17 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:51:06 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| | (b) (4), (b) (6) | |
| User entered '%' | System | 11 Jan 2021 17:39:17 |
| User entered empty. | System | 08 Jan 2021 21:51:06 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[Temperature](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) Jerrica Sullivan (b) (4) | 11 Jan 2021 17:39:17 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:51:06 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:51:06 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Mild (Mild)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:51:06 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:51:06 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:51:06 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:51:06 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:51:06 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Mild (Mild)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:51:06 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Mild (Mild)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:51:06 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:51:06 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:51:06 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:51:06 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:51:06 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:51:06 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:51:06 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:51:06 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:51:06 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Day 2 (Day 2)' | Jerrica Sullivan (b) (4) | 08 Jan 2021 21:51:35 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '03 Jan 2021' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:51:35 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '0' reason for change: Data Entry Error | (b) (4) Jerrica Sullivan (b) (4) | 11 Jan 2021 17:39:17 |
| User entered '1' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:51:35 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) Jerrica Sullivan (b) (4) | 11 Jan 2021 17:39:17 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:51:35 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| | (b) (4), (b) (6) | |
| User entered '%' | System | 11 Jan 2021 17:39:17 |
| User entered empty. | System | 08 Jan 2021 21:51:35 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[Temperature](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) Jerrica Sullivan (b) (4) | 11 Jan 2021 17:39:17 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:51:35 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:51:35 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Mild (Mild)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:51:35 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:51:35 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:51:35 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:51:35 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:51:35 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Mild (Mild)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:51:35 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Mild (Mild)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:51:35 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:51:35 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:51:35 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:51:35 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:51:35 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:51:35 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:51:35 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:51:35 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:51:35 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Day 3 (Day 3)' | Jerrica Sullivan (b) (4) | 08 Jan 2021 21:52:02 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '04 Jan 2021' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:52:02 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '0' reason for change: Data Entry Error | (b) (4) Jerrica Sullivan (b) (4) | 11 Jan 2021 17:39:17 |
| User entered '1' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:52:02 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) Jerrica Sullivan (b) (4) | 11 Jan 2021 17:39:17 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:52:02 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| | (b) (4), (b) (6) | |
| User entered '%' | System | 11 Jan 2021 17:39:17 |
| User entered empty. | System | 08 Jan 2021 21:52:02 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[Temperature](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) Jerrica Sullivan (b) (4) | 11 Jan 2021 17:39:17 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:52:02 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:52:02 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Mild (Mild)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:52:02 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:52:02 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:52:02 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:52:02 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:52:02 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Mild (Mild)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:52:02 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Mild (Mild)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:52:02 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:52:02 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:52:02 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:52:02 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:52:02 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:52:02 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:52:02 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:52:02 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:52:02 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Day 4 (Day 4)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:52:29 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '05 Jan 2021' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:52:29 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '0' reason for change: Data Entry Error | (b) (4) Jerrica Sullivan (b) (4) | 11 Jan 2021 17:39:17 |
| User entered '1' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:52:29 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) Jerrica Sullivan (b) (4) | 11 Jan 2021 17:39:17 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:52:29 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| | (b) (4), (b) (6) | |
| User entered '%' | System | 11 Jan 2021 17:39:17 |
| User entered empty. | System | 08 Jan 2021 21:52:29 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[Temperature](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) Jerrica Sullivan (b) (4) | 11 Jan 2021 17:39:17 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:52:29 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:52:29 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Mild (Mild)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:52:29 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:52:29 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:52:29 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:52:29 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:52:29 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Mild (Mild)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:52:29 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Mild (Mild)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:52:29 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:52:29 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:52:29 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:52:29 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:52:29 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:52:29 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:52:29 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:52:29 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:52:29 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Day 5 (Day 5)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:53:42 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '06 Jan 2021' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:53:42 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '0' reason for change: Data Entry Error | (b) (4) Jerrica Sullivan (b) (4) | 11 Jan 2021 17:39:17 |
| User entered '1' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:53:42 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) Jerrica Sullivan (b) (4) | 11 Jan 2021 17:39:17 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:53:42 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| | (b) (4), (b) (6) | |
| User entered '%' | System | 11 Jan 2021 17:39:17 |
| User entered empty. | System | 08 Jan 2021 21:53:42 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[Temperature](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) Jerrica Sullivan (b) (4) | 11 Jan 2021 17:39:17 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:53:42 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:53:42 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Mild (Mild)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:53:42 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:53:42 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:53:42 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:53:42 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:53:42 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Mild (Mild)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:53:42 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Mild (Mild)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:53:42 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:53:42 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:53:42 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:53:42 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:53:42 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:53:42 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:53:42 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:53:42 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:53:42 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:52

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Day 6 (Day 6)' | Jerrica Sullivan (b) (4) | 08 Jan 2021 21:54:11 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:52

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '07 Jan 2021' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:54:11 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:52

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '0' reason for change: Data Entry Error | (b) (4) Jerrica Sullivan (b) (4) | 11 Jan 2021 17:39:17 |
| User entered '1' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:54:11 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) Jerrica Sullivan (b) (4) | 11 Jan 2021 17:39:17 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:54:11 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| | (b) (4), (b) (6) | |
| User entered '%' | System | 11 Jan 2021 17:39:17 |
| User entered empty. | System | 08 Jan 2021 21:54:11 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:52

[Temperature](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) Jerrica Sullivan (b) (4) | 11 Jan 2021 17:39:17 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:54:11 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:52

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:54:11 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:52

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Mild (Mild)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:54:11 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:52

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:54:11 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:52

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:54:11 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:52

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:54:11 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:52

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:54:11 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:52

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Mild (Mild)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:54:11 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:52

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Mild (Mild)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:54:11 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:54:11 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:54:11 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:52

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:54:11 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:52

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:54:11 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:52

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:54:11 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:52

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:54:11 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:52

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:54:11 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:52

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:54:11 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:52

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Day 7 (Day 7)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:54:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:52

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '08 Jan 2021' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:54:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:52

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '0' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:54:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '99' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:54:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User entered '%' | (b) (4), (b) (6) System | 08 Jan 2021 21:54:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:52

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '98.8' F | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:54:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:52

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:54:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:52

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Mild (Mild)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:54:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:52

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:54:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:52

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:54:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:52

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:54:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:52

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:54:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:52

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Mild (Mild)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:54:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:52

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Mild (Mild)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:54:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:54:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:54:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:52

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:54:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:52

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:54:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:52

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:54:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:52

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:54:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:52

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:54:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:52

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:54:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:52

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Day 8 (Day 8)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:42:30 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:52

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '09 Jan 2021' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:42:30 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:52

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '0' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:42:30 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '97' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:42:30 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User entered '%' | (b) (4), (b) (6) System | 11 Jan 2021 17:42:30 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:52

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '98.4' F | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:42:30 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:52

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:42:30 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:52

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Mild (Mild)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:42:30 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:52

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:42:30 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:52

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:42:30 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:52

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Mild (Mild)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:42:30 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:52

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:42:30 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:52

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Mild (Mild)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:42:30 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:52

[Headache](#)

| Audit | User | Time (GMT) |
|------------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Moderate (Moderate)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:42:30 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:42:30 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:42:30 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:52

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:42:30 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:52

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:42:30 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:52

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:42:30 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:52

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:42:30 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:52

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:42:30 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:52

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:42:30 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:52

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Day 9 (Day 9)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:43:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:52

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '10 Jan 2021' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:43:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:52

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '0' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:43:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '96' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:43:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User entered '%' | (b) (4), (b) (6) System | 11 Jan 2021 17:43:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:52

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '97.9' F | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:43:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:52

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:43:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:52

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Mild (Mild)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:43:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:52

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:43:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:52

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:43:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:52

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Mild (Mild)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:43:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:52

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:43:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:52

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Mild (Mild)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:43:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:52

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Mild (Mild)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:43:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:43:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:43:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:52

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:43:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:52

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:43:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:52

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:43:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:52

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:43:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:52

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:43:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:52

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:43:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:52

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Day 10 (Day 10)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 14:06:51 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:52

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '11 Jan 2021' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 14:06:51 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:52

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '0' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 14:06:51 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '98' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 14:06:51 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User entered '%' | (b) (4), (b) (6) System | 12 Jan 2021 14:06:51 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:52

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '97.6' F | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 14:06:51 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:52

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 14:06:51 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:52

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Mild (Mild)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 14:06:51 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:52

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 14:06:51 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:52

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 14:06:51 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:52

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Mild (Mild)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 14:06:51 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:52

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 14:06:51 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:52

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 14:06:51 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:52

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Mild (Mild)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 14:06:51 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 14:06:51 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 14:06:51 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:52

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 14:06:51 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:52

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 14:06:51 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:52

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 14:06:51 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:52

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 14:06:51 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:52

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 14:06:51 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:52

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 14:06:51 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:52

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Day 11 (Day 11)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 13 Jan 2021 14:45:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:52

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '12 Jan 2021' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 13 Jan 2021 14:45:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:52

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '0' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 13 Jan 2021 14:45:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '97' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 13 Jan 2021 14:45:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User entered '%' | (b) (4), (b) (6) System | 13 Jan 2021 14:45:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:52

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '97.6' F | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 13 Jan 2021 14:45:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:52

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 13 Jan 2021 14:45:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:52

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Mild (Mild)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 13 Jan 2021 14:45:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:52

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 13 Jan 2021 14:45:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:52

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 13 Jan 2021 14:45:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:52

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Mild (Mild)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 13 Jan 2021 14:45:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:52

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 13 Jan 2021 14:45:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:52

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 13 Jan 2021 14:45:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:52

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Mild (Mild)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 13 Jan 2021 14:45:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 13 Jan 2021 14:45:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 13 Jan 2021 14:45:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:52

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 13 Jan 2021 14:45:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:52

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 13 Jan 2021 14:45:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:52

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 13 Jan 2021 14:45:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:52

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 13 Jan 2021 14:45:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:52

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 13 Jan 2021 14:45:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:52

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 13 Jan 2021 14:45:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:52

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Day 12 (Day 12)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 14 Jan 2021 14:16:40 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:52

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '13 Jan 2021' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 14 Jan 2021 14:16:40 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:52

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '0' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 14 Jan 2021 14:16:40 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '97' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 14 Jan 2021 14:16:40 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User entered '%' | (b) (4), (b) (6) System | 14 Jan 2021 14:16:40 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:52

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '97.6' F | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 14 Jan 2021 14:16:40 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:52

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 14 Jan 2021 14:16:40 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:52

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Mild (Mild)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 14 Jan 2021 14:16:40 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:52

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 14 Jan 2021 14:16:40 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:52

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 14 Jan 2021 14:16:40 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:52

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Mild (Mild)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 14 Jan 2021 14:16:40 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:52

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 14 Jan 2021 14:16:40 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:52

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 14 Jan 2021 14:16:40 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:52

[Headache](#)

| Audit | User | Time (GMT) |
|------------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Moderate (Moderate)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 14 Jan 2021 14:16:40 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 14 Jan 2021 14:16:40 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 14 Jan 2021 14:16:40 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:52

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 14 Jan 2021 14:16:40 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:52

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 14 Jan 2021 14:16:40 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:52

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Mild (Mild)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 14 Jan 2021 14:16:40 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:52

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 14 Jan 2021 14:16:40 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:52

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 14 Jan 2021 14:16:40 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:52

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 14 Jan 2021 14:16:40 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:52

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Day 13 (Day 13)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:11:21 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:52

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '14 Jan 2021' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:11:21 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:52

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '0' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:11:21 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '97' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:11:21 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User entered '%' | (b) (4), (b) (6) System | 22 Jan 2021 15:11:21 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:52

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '97.4' F | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:11:21 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:52

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:11:21 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:52

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:11:21 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:52

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:11:21 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:52

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:11:21 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:52

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:11:21 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:52

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:11:21 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:52

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:11:21 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:52

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Mild (Mild)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:11:21 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:11:21 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:11:21 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:52

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:11:21 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:52

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:11:21 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:52

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:11:21 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:52

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:11:21 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:52

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:11:21 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:52

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:11:21 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:52

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Day 14 (Day 14)' | Jerrica Sullivan (b) (4) | 22 Jan 2021 15:13:10 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:52

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '15 Jan 2021' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:13:10 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:52

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '0' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:13:10 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '97' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:13:10 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User entered '%' | (b) (4), (b) (6) System | 22 Jan 2021 15:13:10 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:52

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '97.7' F | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:13:10 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:52

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:13:10 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:52

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:13:10 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:52

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:13:10 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:52

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:13:10 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:52

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:13:10 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:52

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:13:10 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:52

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:13:10 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:52

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:13:10 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:13:10 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:13:10 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:52

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:13:10 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:52

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:13:10 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:52

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:13:10 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:52

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:13:10 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:52

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:13:10 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:52

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:13:10 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:52

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Day 15 (Day 15)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:22 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:52

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '16 Jan 2021' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:22 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:52

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'l' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:22 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:22 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User entered empty. | (b) (4), (b) (6) System | 22 Jan 2021 15:19:22 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:52

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:22 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:52

[Chills](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:22 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:52

[Cough](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:22 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:52

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:22 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:52

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:22 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:52

[Fatigue](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:22 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:52

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:22 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:52

[Body Aches](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:22 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:52

[Headache](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:22 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:22 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:22 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:52

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:22 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:52

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:22 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:52

[Nausea](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:22 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:52

[Vomiting](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:22 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:52

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:22 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:52

[Sore Throat](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:22 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:52

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Day 16 (Day 16)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:52

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '17 Jan 2021' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:52

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'I' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User entered empty. | (b) (4), (b) (6) System | 22 Jan 2021 15:19:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:52

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:52

[Chills](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:52

[Cough](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:52

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:52

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:52

[Fatigue](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:52

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:52

[Body Aches](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:52

[Headache](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:52

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:52

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:52

[Nausea](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:52

[Vomiting](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:52

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:52

[Sore Throat](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:34 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:05:52

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Day 17 (Day 17)' | Jerrica Sullivan (b) (4) | 22 Jan 2021 15:19:44 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:05:52

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '18 Jan 2021' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:05:52

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'l' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User entered empty. | (b) (4), (b) (6) System | 22 Jan 2021 15:19:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:05:52

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:05:52

[Chills](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:05:52

[Cough](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:05:52

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:05:52

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:05:52

[Fatigue](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:05:52

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:05:52

[Body Aches](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:05:52

[Headache](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:05:52

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:05:52

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:05:52

[Nausea](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:05:52

[Vomiting](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:05:52

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:05:52

[Sore Throat](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:44 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:05:52

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Day 18 (Day 18)' | Jerrica Sullivan (b) (4) | 22 Jan 2021 15:19:55 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:05:52

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '19 Jan 2021' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:55 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:05:52

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'I' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:55 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:55 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User entered empty. | (b) (4), (b) (6) System | 22 Jan 2021 15:19:55 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:05:52

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:55 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:05:52

[Chills](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:55 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:05:52

[Cough](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:55 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:05:52

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:55 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:05:52

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:55 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:05:52

[Fatigue](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:55 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:05:52

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:55 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:05:52

[Body Aches](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:55 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:05:52

[Headache](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:55 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:55 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:55 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:05:52

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:55 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:05:52

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:55 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:05:52

[Nausea](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:55 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:05:52

[Vomiting](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:55 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:05:52

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:55 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:05:52

[Sore Throat](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:19:55 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:05:52

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Day 19 (Day 19)' | Jerrica Sullivan (b) (4) | 22 Jan 2021 15:20:35 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:05:52

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '20 Jan 2021' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:20:35 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:05:52

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '0' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:20:35 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '97' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:20:35 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User entered '%' | (b) (4), (b) (6) System | 22 Jan 2021 15:20:35 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:05:52

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '97.6' F | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:20:35 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:05:52

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:20:35 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:05:52

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:20:35 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:05:52

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:20:35 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:05:52

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:20:35 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:05:52

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:20:35 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:05:52

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:20:35 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:05:52

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:20:35 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:05:52

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:20:35 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:20:35 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:20:35 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:05:52

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:20:35 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:05:52

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:20:35 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:05:52

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:20:35 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:05:52

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:20:35 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:05:52

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:20:35 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:05:52

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:20:35 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:05:52

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Day 20 (Day 20)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:21:18 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:05:52

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '21 Jan 2021' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:21:18 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:05:52

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '0' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:21:18 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '94' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:21:18 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User entered '%' | (b) (4), (b) (6) System | 22 Jan 2021 15:21:18 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:05:52

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '98.4' F | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:21:18 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:05:52

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:21:18 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:05:52

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:21:18 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:05:52

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:21:18 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:05:52

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:21:18 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:05:52

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:21:18 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:05:52

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:21:18 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:05:52

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:21:18 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:05:52

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:21:18 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:21:18 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:21:18 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:05:52

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:21:18 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:05:52

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:21:18 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:05:52

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:21:18 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:05:52

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:21:18 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:05:52

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:21:18 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:05:52

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 15:21:18 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:05:52

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Day 21 (Day 21)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:16:09 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:05:52

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '22 Jan 2021' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:16:09 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:05:52

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '0' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:16:09 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '97' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:16:09 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User entered '%' | (b) (4), (b) (6) System | 25 Jan 2021 17:16:09 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:05:52

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '98.5' F | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:16:09 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:05:52

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:16:09 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:05:52

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:16:09 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:05:52

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:16:09 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:05:52

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:16:09 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:05:52

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:16:09 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:05:52

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:16:09 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:05:52

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:16:09 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:05:52

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:16:09 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:16:09 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:16:09 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:05:52

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:16:09 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:05:52

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:16:09 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:05:52

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:16:09 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:05:52

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:16:09 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:05:52

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:16:09 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:05:52

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:16:09 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:05:52

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Day 22 (Day 22)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:16:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:05:52

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '23 Jan 2021' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:16:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:05:52

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '0' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:16:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '96' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:16:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User entered '%' | (b) (4), (b) (6) System | 25 Jan 2021 17:16:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:05:52

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '99.5' F | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:16:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:05:52

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:16:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:05:52

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:16:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:05:52

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:16:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:05:52

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:16:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:05:52

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:16:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:05:52

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:16:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:05:52

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:16:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:05:52

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:16:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:16:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:16:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:05:52

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:16:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:05:52

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:16:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:05:52

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:16:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:05:52

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:16:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:05:52

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:16:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:05:52

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:16:47 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:05:52

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Day 23 (Day 23)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:17:36 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:05:52

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '24 Jan 2021' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:17:36 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:05:52

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '0' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:17:36 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '97' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:17:36 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User entered '%' | (b) (4), (b) (6) System | 25 Jan 2021 17:17:36 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:05:52

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '97.7' F | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:17:36 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:05:52

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:17:36 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:05:52

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:17:36 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:05:52

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:17:36 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:05:52

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:17:36 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:05:52

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:17:36 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:05:52

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:17:36 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:05:52

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:17:36 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:05:52

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:17:36 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:17:36 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:17:36 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:05:52

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:17:36 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:05:52

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:17:36 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:05:52

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:17:36 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:05:52

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:17:36 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:05:52

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:17:36 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:05:52

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 25 Jan 2021 17:17:36 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:05:52

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Day 24 (Day 24)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 23:12:41 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:05:52

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '25 Jan 2021' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 23:12:41 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:05:52

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '0' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 23:12:41 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '94' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 23:12:41 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User entered '%' | (b) (4), (b) (6) System | 27 Jan 2021 23:12:41 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:05:52

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '98.7' F | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 23:12:41 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:05:52

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 23:12:41 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:05:52

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 23:12:41 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:05:52

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 23:12:41 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:05:52

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 23:12:41 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:05:52

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 23:12:41 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:05:52

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 23:12:41 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:05:52

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 23:12:41 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:05:52

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 23:12:41 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 23:12:41 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 23:12:41 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:05:52

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 23:12:41 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:05:52

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 23:12:41 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:05:52

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 23:12:41 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:05:52

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 23:12:41 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:05:52

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 23:12:41 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:05:52

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 23:12:41 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:05:52

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Day 25 (Day 25)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 23:13:28 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:05:52

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '26 Jan 2021' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 23:13:28 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:05:52

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '0' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 23:13:28 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '97' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 23:13:28 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User entered '%' | (b) (4), (b) (6) System | 27 Jan 2021 23:13:28 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:05:52

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '98.6' F | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 23:13:28 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:05:52

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 23:13:28 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:05:52

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 23:13:28 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:05:52

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 23:13:28 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:05:52

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 23:13:28 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:05:52

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 23:13:28 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:05:52

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 23:13:28 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:05:52

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 23:13:28 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:05:52

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 23:13:28 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 23:13:28 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 23:13:28 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:05:52

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 23:13:28 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:05:52

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 23:13:28 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:05:52

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 23:13:28 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:05:52

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 23:13:28 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:05:52

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 23:13:28 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:05:52

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 23:13:28 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:05:52

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Day 26 (Day 26)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 28 Jan 2021 13:46:03 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:05:52

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '27 Jan 2021' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 28 Jan 2021 13:46:03 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:05:52

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '0' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 28 Jan 2021 13:46:03 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '91' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 28 Jan 2021 13:46:03 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User entered '%' | (b) (4), (b) (6) System | 28 Jan 2021 13:46:03 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:05:52

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '98.7' F | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 28 Jan 2021 13:46:03 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:05:52

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 28 Jan 2021 13:46:03 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:05:52

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 28 Jan 2021 13:46:03 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:05:52

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 28 Jan 2021 13:46:03 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:05:52

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 28 Jan 2021 13:46:03 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:05:52

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 28 Jan 2021 13:46:03 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:05:52

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 28 Jan 2021 13:46:03 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:05:52

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 28 Jan 2021 13:46:03 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:05:52

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Mild (Mild)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 28 Jan 2021 13:46:03 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 28 Jan 2021 13:46:03 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 28 Jan 2021 13:46:03 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:05:52

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 28 Jan 2021 13:46:03 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:05:52

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 28 Jan 2021 13:46:03 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:05:52

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 28 Jan 2021 13:46:03 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:05:52

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 28 Jan 2021 13:46:03 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:05:52

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 28 Jan 2021 13:46:03 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:05:52

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 28 Jan 2021 13:46:03 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:05:52

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Day 27 (Day 27)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 29 Jan 2021 15:14:39 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:05:52

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '28 Jan 2021' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 29 Jan 2021 15:14:39 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:05:52

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '0' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 29 Jan 2021 15:14:39 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '97' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 29 Jan 2021 15:14:39 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| User entered '%' | (b) (4), (b) (6) System | 29 Jan 2021 15:14:39 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:05:52

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '97.7' F | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 29 Jan 2021 15:14:39 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:05:52

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 29 Jan 2021 15:14:39 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:05:52

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 29 Jan 2021 15:14:39 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:05:52

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 29 Jan 2021 15:14:39 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:05:52

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 29 Jan 2021 15:14:39 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:05:52

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 29 Jan 2021 15:14:39 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:05:52

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 29 Jan 2021 15:14:39 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:05:52

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 29 Jan 2021 15:14:39 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:05:52

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 29 Jan 2021 15:14:39 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 29 Jan 2021 15:14:39 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 29 Jan 2021 15:14:39 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:05:52

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 29 Jan 2021 15:14:39 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:05:52

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 29 Jan 2021 15:14:39 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:05:52

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 29 Jan 2021 15:14:39 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:05:52

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 29 Jan 2021 15:14:39 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:05:52

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 29 Jan 2021 15:14:39 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:05:52

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:31:57 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'None (None)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 29 Jan 2021 15:14:39 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:05:52

[Date of Visit](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:02 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:17 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User closed query 'Per GCL Lab Reconciliation: Swab: Response to previous query: Response noted, however please provide both Accession number and the tracking details in the response. Thank you.' (Site from DM). | (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) | 02 Feb 2021 11:39:40 |
| Query 'Per GCL Lab Reconciliation: Swab: Response to previous query: Response noted, however please provide both Accession number and the tracking details in the response. Thank you.' answered with '1F69031 accession number was provided in previous query sample shipped 08jan2021. no tracking number available ' (Site from DM). | Jerrica Sullivan (b) (4) (b) (4) | 27 Jan 2021 14:27:46 |
| User opened query 'Per GCL Lab Reconciliation: Swab: Response to previous query: Response noted, however please provide both Accession number and the tracking details in the response. Thank you.' (Site from DM). | (b) (4), (b) (6) (b) (4), (b) (6) | 27 Jan 2021 11:20:13 |
| User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 08JAN2021 is recorded under Covid-19 Assessment in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number and tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM). | (b) (4), (b) (6) (b) (4), (b) (6) | 19 Jan 2021 09:22:10 |
| Query 'Per GCL Lab Reconciliation: Swab: Sample dated 08JAN2021 is recorded under Covid-19 Assessment in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number and tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with '1F69031, accession number of processed nasal swab for collection on 08jan2021' (Site from DM). | Jerrica Sullivan (b) (4) (b) (4) | 13 Jan 2021 13:46:23 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:05:52

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:02 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:17 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Yes (Y)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:48:42 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:05:52

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:02 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:17 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System). | (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) | 13 Jan 2021 12:55:42 |
| Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'confirmed ' (Site from System). | Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 15:52:34 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 12 Jan 2021 15:52:21 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 12 Jan 2021 15:52:21 |
| User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System). | System | 12 Jan 2021 15:52:21 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 15:52:21 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 08 Jan 2021 21:48:42 |
| User entered empty. | Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:48:42 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:05:52

[Date of Test](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:02 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:17 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '08 Jan 2021' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:48:42 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:05:52

[Type of Test Performed](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:02 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:17 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:48:42 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:05:52

[Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:02 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:17 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:48:42 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:05:52

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:02 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:17 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'No (N)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:48:42 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:05:52

[Lab/ Institution Test Performed](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:02 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:17 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:48:42 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:05:52

[CLIA Certified?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:02 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:17 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 08 Jan 2021 21:48:42 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:05:52

[COVID-19 Positive \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:02 |
| User entered 'I' | (b) (4), (b) (6) System | 12 Jan 2021 15:52:21 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

Did the subject have Respiratory Rates \geq 30 per Minute?

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'No (N)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[Respiratory Rate](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

Did the subject have Heart Rate \geq 125 beats per minute

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'No (N)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[Heart Rate](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?

| Audit | User | Time (GMT) |
|------------------------------------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4) Jerrica Sullivan (b) (4) | 29 Jan 2021 16:02:30 |
| User entered 'No (N)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[Start Date](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '27 Jan 2021' reason for change: Data Entry Error | (b) (4) Jerrica Sullivan (b) (4) | 29 Jan 2021 16:03:09 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[End Date](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '28 Jan 2021' reason for change: Data Entry Error | (b) (4) Jerrica Sullivan (b) (4) | 29 Jan 2021 16:03:09 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[Oxygen Saturation](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '91' reason for change: Data Entry Error | (b) (4) Jerrica Sullivan (b) (4) | 29 Jan 2021 16:02:30 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'No (N)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[PaO2](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

Did the subject have Respiratory failure?

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'No (N)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'No (N)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[High-Flow Oxygen?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[Non-Invasive Ventilation?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[Mechanical Ventilation?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[ECMO?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'No (N)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[Evidence of Shock Requires
Vasopressors](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[Acute Renal Dysfunction?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[Hepatic Dysfunction?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[Neurologic Dysfunction?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[Clinical Evidence](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'No (N)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[Date of Assessment](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[Radiographical Evidence](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'No (N)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[Date of Assessment](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[Admission to an intensive care unit due to SARS-CoV-2](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'No (N)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:05:52

[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:13 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:29 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:19:07 |

US3232056

Folder: Covid-19 Assessment 08 Jan 2021

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:05:52

[Generate Next COVID-19 Assessment](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:32:20 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Apr 2021 14:45:39 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'No (N)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 08 Mar 2021 21:38:21 |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:05:52

[Date of Contact](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '16 Apr 2021' | Adreanna Pou (b) (4) | 19 Apr 2021 21:44:27 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:05:52

[Time of Contact](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '14:33' | Adreanna Pou (b) (4) | 19 Apr 2021 21:44:27 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:05:52

[Date and Time of Contact \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '16 Apr 2021 14:33' | System | 19 Apr 2021 21:44:27 |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:05:52

[Type of Contact](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled) | Adreanna Pou (b) (4) | 19 Apr 2021 21:44:27 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:05:52

[Has the subject reported symptoms of SARS-COV-2?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:44:27 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Day 1 (Day 1)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:47:33 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '16 Apr 2021' | Adreanna Pou (b) (4) | 19 Apr 2021 21:47:33 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 21:47:33 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '96' | Adreanna Pou (b) (4) | 19 Apr 2021 21:47:33 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '%' | System | 19 Apr 2021 21:47:33 |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '98.3' F | Adreanna Pou (b) (4) | 19 Apr 2021 21:47:33 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:47:33 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:47:33 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:47:33 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:47:33 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Mild (Mild)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:47:33 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:47:33 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:47:33 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[Headache](#)

| Audit | User | Time (GMT) |
|------------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Moderate (Moderate)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:47:33 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:47:33 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:47:33 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|------------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Moderate (Moderate)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:47:33 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:47:33 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:47:33 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:47:33 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:47:33 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:52

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:47:33 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Day 2 (Day 2)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:49:08 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '17 Apr 2021' | Adreanna Pou (b) (4) | 19 Apr 2021 21:49:08 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 21:49:08 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '94' | Adreanna Pou (b) (4) | 19 Apr 2021 21:49:08 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '%' | System | 19 Apr 2021 21:49:08 |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '97.7' F | Adreanna Pou (b) (4) | 19 Apr 2021 21:49:08 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:49:08 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:49:08 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:49:08 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:49:08 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:49:08 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:49:08 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:49:08 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:49:08 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:49:08 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:49:08 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:49:08 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:49:08 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:49:08 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:49:08 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:49:08 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:52

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:49:08 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Day 3 (Day 3)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:50:06 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '18 Apr 2021' | Adreanna Pou (b) (4) | 19 Apr 2021 21:50:06 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 21:50:06 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '91' | Adreanna Pou (b) (4) | 19 Apr 2021 21:50:06 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '%' | System | 19 Apr 2021 21:50:06 |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '98' F | Adreanna Pou (b) (4) | 19 Apr 2021 21:50:06 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:50:06 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:50:06 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:50:06 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:50:06 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:50:06 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:50:06 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:50:06 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:50:06 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:50:06 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:50:06 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:50:06 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:50:06 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:50:06 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:50:06 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:50:06 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:52

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:50:06 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Day 4 (Day 4)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:51:10 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '19 Apr 2021' | Adreanna Pou (b) (4) | 19 Apr 2021 21:51:10 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 21:51:10 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '95' | Adreanna Pou (b) (4) | 19 Apr 2021 21:51:10 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '%' | System | 19 Apr 2021 21:51:10 |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '98.4' F | Adreanna Pou (b) (4) | 19 Apr 2021 21:51:10 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:51:10 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:51:10 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:51:10 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:51:10 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:51:10 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:51:10 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:51:10 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:51:10 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:51:10 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:51:10 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:51:10 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:51:10 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:51:10 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:51:10 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:51:10 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:52

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:51:10 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Day 5 (Day 5)' | Adreanna Pou (b) (4) | 20 Apr 2021 21:24:06 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '20 Apr 2021' | Adreanna Pou (b) (4) | 20 Apr 2021 21:24:06 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 20 Apr 2021 21:24:06 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '95' | Adreanna Pou (b) (4) | 20 Apr 2021 21:24:06 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '%' | System | 20 Apr 2021 21:24:06 |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '98.4' F | Adreanna Pou (b) (4) | 20 Apr 2021 21:24:06 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 20 Apr 2021 21:24:06 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 20 Apr 2021 21:24:06 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 20 Apr 2021 21:24:06 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 20 Apr 2021 21:24:06 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 20 Apr 2021 21:24:06 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 20 Apr 2021 21:24:06 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 20 Apr 2021 21:24:06 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 20 Apr 2021 21:24:06 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 20 Apr 2021 21:24:06 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 20 Apr 2021 21:24:06 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 20 Apr 2021 21:24:06 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 20 Apr 2021 21:24:06 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 20 Apr 2021 21:24:06 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 20 Apr 2021 21:24:06 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 20 Apr 2021 21:24:06 |
| | (b) (4) | |

US3232056

Folder: Covid-19 Assessment 16 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:52

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (None)' | Adreanna Pou (b) (4) | 20 Apr 2021 21:24:06 |
| | (b) (4) | |

US3232056

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:05:52

[Visit](#)

| Audit | User | Time (GMT) |
|---------------------------------------------|-------------------------------------|----------------------|
| User accepted default value 'Day 3 (Day 3)' | Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:43:58 |

US3232056

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:05:52

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 17 Mar 2021 15:55:21 |
| | (b) (4), (b) (6) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 11 Jan 2021 17:43:58 |
| | (b) (4) | |

US3232056

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:05:52

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 17 Mar 2021 15:55:21 |
| | (b) (4), (b) (6) | |
| User closed query 'Per GCL Lab Recon: Saliva: Sample dated 10-JAN-2021 for Day 3 is recorded in EDC, however sample is reported with 08-JAN-2021 for Day 3 in PPD Central lab. Please confirm the correct date and update if applicable, thank you. ' (Site from DM). | (b) (4), (b) (6) | 24 Feb 2021 12:58:11 |
| Query 'Per GCL Lab Recon: Saliva: Sample dated 10-JAN-2021 for Day 3 is recorded in EDC, however sample is reported with 08-JAN-2021 for Day 3 in PPD Central lab. Please confirm the correct date and update if applicable, thank you. ' answered with 'Date change request submitted, collection date is 10Jan2021' (Site from DM). | Jerrica Sullivan (b) (4) | 10 Feb 2021 13:57:04 |
| | (b) (4) | |
| User opened query 'Per GCL Lab Recon: Saliva: Sample dated 10-JAN-2021 for Day 3 is recorded in EDC, however sample is reported with 08-JAN-2021 for Day 3 in PPD Central lab. Please confirm the correct date and update if applicable, thank you. ' (Site from DM). | (b) (4), (b) (6) | 10 Feb 2021 09:37:32 |
| | (b) (4), (b) (6) | |
| User entered '10 Jan 2021' | Jerrica Sullivan (b) (4) | 11 Jan 2021 17:43:58 |
| | (b) (4) | |

US3232056

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:05:52

[Visit](#)

| Audit | User | Time (GMT) |
|---------------------------------------------|-------------------------------------|----------------------|
| User accepted default value 'Day 5 (Day 5)' | Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:43:58 |

US3232056

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:05:52

Was Saliva Collected?

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 17 Mar 2021 15:55:21 |
| | (b) (4), (b) (6) | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 13 Jan 2021 14:44:51 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 13 Jan 2021 14:44:51 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) | 13 Jan 2021 14:44:51 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 11 Jan 2021 17:43:58 |
| User entered empty. | Jerrica Sullivan (b) (4) | 11 Jan 2021 17:43:58 |
| | (b) (4) | |

US3232056

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:05:52

[Date of Collection](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 17 Mar 2021 15:55:21 |
| | (b) (4), (b) (6) | |
| User entered '12 Jan 2021' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) | 13 Jan 2021 14:44:51 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 11 Jan 2021 17:43:58 |
| | (b) (4) | |

US3232056

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:05:52

[Visit](#)

| Audit | User | Time (GMT) |
|---------------------------------------------|-------------------------------------|----------------------|
| User accepted default value 'Day 7 (Day 7)' | Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:43:58 |

US3232056

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:05:52

Was Saliva Collected?

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 17 Mar 2021 15:55:21 |
| | (b) (4), (b) (6) | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 22 Jan 2021 15:22:05 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 22 Jan 2021 15:22:05 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) | 22 Jan 2021 15:22:05 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 11 Jan 2021 17:43:58 |
| User entered empty. | Jerrica Sullivan (b) (4) | 11 Jan 2021 17:43:58 |
| | (b) (4) | |

US3232056

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:05:52

[Date of Collection](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 17 Mar 2021 15:55:21 |
| | (b) (4), (b) (6) | |
| User entered '14 Jan 2021' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) | 22 Jan 2021 15:22:05 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 11 Jan 2021 17:43:58 |
| | (b) (4) | |

US3232056

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:05:52

[Visit](#)

| Audit | User | Time (GMT) |
|---------------------------------------------|-------------------------------------|----------------------|
| User accepted default value 'Day 9 (Day 9)' | Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:43:58 |

US3232056

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:05:52

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 17 Mar 2021 15:55:21 |
| | (b) (4), (b) (6) | |
| User closed query 'Per ETRTR, Please confirm response and update as needed. According to PPD labs, saliva sample was collected for day 9' (Site from CRA). | (b) (4), (b) (6) | 17 Mar 2021 15:55:14 |
| | (b) (4), (b) (6) | |
| Query 'Per ETRTR, Please confirm response and update as needed. According to PPD labs, saliva sample was collected for day 9' answered with '1F69031, Accession number of processed sample, data error ' (Site from CRA). | Jerrica Sullivan (b) (4) | 02 Feb 2021 14:15:39 |
| | (b) (4) | |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) | 02 Feb 2021 14:15:11 |
| | (b) (4) | |
| User opened query 'Per ETRTR, Please confirm response and update as needed. According to PPD labs, saliva sample was collected for day 9' (Site from CRA). | (b) (4), (b) (6) | 01 Feb 2021 00:25:14 |
| | (b) (4), (b) (6) | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 22 Jan 2021 15:22:05 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 22 Jan 2021 15:22:05 |
| User entered 'No (N)' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) | 22 Jan 2021 15:22:05 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 11 Jan 2021 17:43:58 |
| User entered empty. | Jerrica Sullivan (b) (4) | 11 Jan 2021 17:43:58 |
| | (b) (4) | |

US3232056

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:05:52

[Date of Collection](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 17 Mar 2021 15:55:21 |
| | (b) (4), (b) (6) | |
| User entered '16 Jan 2021' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) | 05 Feb 2021 19:10:01 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 11 Jan 2021 17:43:58 |
| | (b) (4) | |

US3232056

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:05:52

[Visit](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------|-------------------------------------|----------------------|
| User accepted default value 'Day 14 (Day 14)' | Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:43:58 |

US3232056

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:05:52

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 17 Mar 2021 15:55:21 |
| | (b) (4), (b) (6) | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 22 Jan 2021 15:22:05 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 22 Jan 2021 15:22:05 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) | 22 Jan 2021 15:22:05 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 11 Jan 2021 17:43:58 |
| User entered empty. | Jerrica Sullivan (b) (4) | 11 Jan 2021 17:43:58 |
| | (b) (4) | |

US3232056

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:05:52

[Date of Collection](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 17 Mar 2021 15:55:21 |
| | (b) (4), (b) (6) | |
| User entered '21 Jan 2021' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) | 22 Jan 2021 15:22:05 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 11 Jan 2021 17:43:58 |
| | (b) (4) | |

US3232056

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:05:52

[Visit](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------|-------------------------------------|----------------------|
| User accepted default value 'Day 21 (Day 21)' | Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:43:58 |

US3232056

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:05:52

Was Saliva Collected?

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 17 Mar 2021 15:55:21 |
| | (b) (4), (b) (6) | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 29 Jan 2021 15:15:52 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 29 Jan 2021 15:15:52 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:15:52 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 11 Jan 2021 17:43:58 |
| User entered empty. | Jerrica Sullivan (b) (4) | 11 Jan 2021 17:43:58 |
| | (b) (4) | |

US3232056

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:05:52

[Date of Collection](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 17 Mar 2021 15:55:21 |
| | (b) (4), (b) (6) | |
| User entered '28 Jan 2021' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:15:52 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 11 Jan 2021 17:43:58 |
| | (b) (4) | |

US3232056

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:05:52

[Visit](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------|-------------------------------------|----------------------|
| User accepted default value 'Day 28 (Day 28)' | Jerrica Sullivan (b) (4) (b) (4) | 11 Jan 2021 17:43:58 |

US3232056

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:05:52

Was Saliva Collected?

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 17 Mar 2021 15:55:21 |
| | (b) (4), (b) (6) | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 05 Feb 2021 19:09:27 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 05 Feb 2021 19:09:27 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) | 05 Feb 2021 19:09:27 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 11 Jan 2021 17:43:58 |
| User entered empty. | Jerrica Sullivan (b) (4) | 11 Jan 2021 17:43:58 |
| | (b) (4) | |

US3232056

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:05:52

[Date of Collection](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 17 Mar 2021 15:55:21 |
| | (b) (4), (b) (6) | |
| User entered '05 Feb 2021' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) | 05 Feb 2021 19:09:27 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 11 Jan 2021 17:43:58 |
| | (b) (4) | |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:52

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 18 Mar 2021 15:26:15 |
| | (b) (4), (b) (6) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 08 Jan 2021 21:49:01 |
| | (b) (4) | |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:52

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 18 Mar 2021 15:26:15 |
| | (b) (4), (b) (6) | |
| User entered '08 Jan 2021' | Jerrica Sullivan (b) (4) | 08 Jan 2021 21:49:01 |
| | (b) (4) | |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:52

Was visit performed at the participant's home or at the clinic?

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 18 Mar 2021 15:26:15 |
| | (b) (4), (b) (6) | |
| User entered 'Clinic (Clinic)' | Jerrica Sullivan (b) (4) | 08 Jan 2021 21:49:01 |
| | (b) (4) | |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:52

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|--------|----------------------|
| User entered 'SICKD1' | System | 08 Jan 2021 21:49:01 |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 18 Mar 2021 15:26:22 |
| | (b) (4), (b) (6) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 08 Jan 2021 21:49:33 |
| | (b) (4) | |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 18 Mar 2021 15:26:22 |
| | (b) (4), (b) (6) | |
| User entered '08 Jan 2021' | Jerrica Sullivan (b) (4) | 08 Jan 2021 21:49:33 |
| | (b) (4) | |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 18 Mar 2021 15:26:22 |
| | (b) (4), (b) (6) | |
| User entered '12:10' | Jerrica Sullivan (b) (4) | 08 Jan 2021 21:49:33 |
| | (b) (4) | |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '08 Jan 2021 12:10' | System | 08 Jan 2021 21:49:33 |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Height (xxx.x)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| DataPoint set to visible. | System | 19 Apr 2021 21:35:23 |
| Signature has been broken. | System | 19 Apr 2021 21:35:09 |
| DataPoint set to invisible. | System | 19 Apr 2021 21:35:09 |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Mar 2021 15:26:22 |
| | (b) (4), (b) (6) | |
| User entered '155' cm reason for change: Data Entry Error | Jerrica Sullivan (b) (4) | 08 Jan 2021 21:49:53 |
| | (b) (4) | |
| User entered missing code ND - Not Done. | Jerrica Sullivan (b) (4) | 08 Jan 2021 21:49:33 |
| | (b) (4) | |
| DataPoint set to visible. | System | 08 Jan 2021 21:49:01 |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Weight (xxx.x)

| Audit | User | Time (GMT) |
|-----------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| DataPoint set to visible. | System | 19 Apr 2021 21:35:23 |
| Signature has been broken. | System | 19 Apr 2021 21:35:09 |
| DataPoint set to invisible. | System | 19 Apr 2021 21:35:09 |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Mar 2021 15:26:22 |
| | (b) (4), (b) (6) | |
| User entered '59.9' kg | Jerrica Sullivan (b) (4) | 08 Jan 2021 21:49:33 |
| | (b) (4) | |
| DataPoint set to visible. | System | 08 Jan 2021 21:49:01 |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 18 Mar 2021 15:26:22 |
| | (b) (4), (b) (6) | |
| User entered '98.8' F | Jerrica Sullivan (b) (4) | 08 Jan 2021 21:49:33 |
| | (b) (4) | |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 18 Mar 2021 15:26:22 |
| | (b) (4), (b) (6) | |
| User entered 'Oral (Oral)' | Jerrica Sullivan (b) (4) | 08 Jan 2021 21:49:33 |
| | (b) (4) | |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 18 Mar 2021 15:26:22 |
| | (b) (4), (b) (6) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 08 Jan 2021 21:49:33 |
| | (b) (4) | |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 18 Mar 2021 15:26:22 |
| | (b) (4), (b) (6) | |
| User entered '69' | Jerrica Sullivan (b) (4) | 08 Jan 2021 21:49:33 |
| | (b) (4) | |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 08 Jan 2021 21:49:33 |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 18 Mar 2021 15:26:22 |
| | (b) (4), (b) (6) | |
| User entered '22' | Jerrica Sullivan (b) (4) | 08 Jan 2021 21:49:33 |
| | (b) (4) | |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 08 Jan 2021 21:49:33 |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 18 Mar 2021 15:26:22 |
| | (b) (4), (b) (6) | |
| User entered '179' | Jerrica Sullivan (b) (4) | 08 Jan 2021 21:49:33 |
| | (b) (4) | |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 08 Jan 2021 21:49:33 |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| Signature has been broken indirectly. | System | 19 Apr 2021 21:35:09 |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Mar 2021 15:26:22 |
| | (b) (4), (b) (6) | |
| User entered '72' | Jerrica Sullivan (b) (4) | 08 Jan 2021 21:49:33 |
| | (b) (4) | |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 08 Jan 2021 21:49:33 |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:52

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 18 Mar 2021 15:26:31 |
| | (b) (4), (b) (6) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 08 Jan 2021 21:50:21 |
| | (b) (4) | |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:52

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 18 Mar 2021 15:26:31 |
| | (b) (4), (b) (6) | |
| User entered '08 Jan 2021' | Jerrica Sullivan (b) (4) | 08 Jan 2021 21:50:21 |
| | (b) (4) | |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:05:52

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 18 Mar 2021 15:26:37 |
| | (b) (4), (b) (6) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 08 Jan 2021 21:50:09 |
| | (b) (4) | |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:05:52

[Date of Collection](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 18 Mar 2021 15:26:37 |
| | (b) (4), (b) (6) | |
| User entered '08 Jan 2021' | Jerrica Sullivan (b) (4) | 08 Jan 2021 21:50:09 |
| | (b) (4) | |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:52

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 19 Apr 2021 21:35:23 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 19 Apr 2021 21:35:23 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Adreanna Pou (b) (4) | 19 Apr 2021 21:35:23 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 19 Apr 2021 21:35:09 |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 21:35:09 |
| | (b) (4) | |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:52

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '16 Apr 2021' reason for change: Data Entry Error | Adreanna Pou (b) (4) | 19 Apr 2021 21:35:23 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 21:35:09 |
| | (b) (4) | |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:52

Was visit performed at the participant's home or at the clinic?

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User closed query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System). | System | 19 Apr 2021 21:35:33 |
| User entered 'Clinic (Clinic)' reason for change: Data Entry Error | Adreanna Pou (b) (4) | 19 Apr 2021 21:35:33 |
| | (b) (4) | |
| User opened query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System). | System | 19 Apr 2021 21:35:23 |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 21:35:09 |
| | (b) (4) | |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:52

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|--------|----------------------|
| User entered 'SICKD1' | System | 19 Apr 2021 21:35:23 |
| User entered empty. | System | 19 Apr 2021 21:35:09 |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:41:14 |
| | (b) (4) | |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '16 Apr 2021' | Adreanna Pou (b) (4) | 19 Apr 2021 21:41:14 |
| | (b) (4) | |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '14:33' | Adreanna Pou (b) (4) | 19 Apr 2021 21:41:14 |
| | (b) (4) | |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '16 Apr 2021 14:33' | System | 19 Apr 2021 21:41:14 |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Height (xxx.x)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '156' cm reason for change: Data Entry Error | Adreanna Pou (b) (4) | 19 Apr 2021 21:42:54 |
| | (b) (4) | |
| User entered '126' cm | Adreanna Pou (b) (4) | 19 Apr 2021 21:41:14 |
| | (b) (4) | |
| DataPoint set to visible. | System | 19 Apr 2021 21:35:23 |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Weight (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '54' kg | Adreanna Pou (b) (4) | 19 Apr 2021 21:41:14 |
| | (b) (4) | |
| DataPoint set to visible. | System | 19 Apr 2021 21:35:23 |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '98.3' F | Adreanna Pou (b) (4) | 19 Apr 2021 21:41:14 |
| | (b) (4) | |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Oral (Oral)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:41:14 |
| | (b) (4) | |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 21:41:14 |
| | (b) (4) | |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '71' | Adreanna Pou (b) (4) | 19 Apr 2021 21:41:14 |
| | (b) (4) | |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 19 Apr 2021 21:41:14 |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '12' | Adreanna Pou (b) (4) | 19 Apr 2021 21:41:14 |
| | (b) (4) | |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 19 Apr 2021 21:41:14 |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '116' | Adreanna Pou (b) (4) | 19 Apr 2021 21:41:14 |
| | (b) (4) | |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 19 Apr 2021 21:41:14 |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) | 20 Apr 2021 07:57:45 |
| Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System). | Adreanna Pou (b) (4) (b) (4) | 19 Apr 2021 21:43:01 |
| User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | | 19 Apr 2021 21:41:14 |
| User entered '57' | Adreanna Pou (b) (4) (b) (4) | 19 Apr 2021 21:41:14 |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 19 Apr 2021 21:41:14 |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:52

Was the physical examination performed?

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:43:19 |
| | (b) (4) | |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:52

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '16 Apr 2021' | Adreanna Pou (b) (4) | 19 Apr 2021 21:43:19 |
| | (b) (4) | |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:05:52

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:43:27 |
| | (b) (4) | |

US3232056

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:05:52

[Date of Collection](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '16 Apr 2021' | Adreanna Pou (b) (4) | 19 Apr 2021 21:43:27 |
| | (b) (4) | |

US3232056

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:52

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:21:06 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Mar 2021 15:26:48 |
| | (b) (4), (b) (6) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 05 Feb 2021 18:54:53 |
| | (b) (4) | |

US3232056

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:52

Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:21:06 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Mar 2021 15:26:48 |
| | (b) (4), (b) (6) | |
| User entered '05 Feb 2021' | Jerrica Sullivan (b) (4) | 05 Feb 2021 18:54:53 |
| | (b) (4) | |

US3232056

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:52

Was visit performed at the participant's home or at the clinic?

| Audit | User | Time (GMT) |
|--------------------------------|---------------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:21:06 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 18 Mar 2021 15:26:48 |
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4) | 05 Feb 2021 18:54:53 |

US3232056

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:52

[Folder OID](#)

| Audit | User | Time (GMT) |
|------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:21:06 |
| User entered 'SICKD28' | (b) (4), (b) (6) System | 05 Feb 2021 18:54:53 |

US3232056

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:20:58 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 18 Mar 2021 15:26:53 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4) | 05 Feb 2021 18:55:43 |

US3232056

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:20:58 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 18 Mar 2021 15:26:53 |
| User entered '05 Feb 2021' | (b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4) | 05 Feb 2021 18:55:43 |

US3232056

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:20:58 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 18 Mar 2021 15:26:53 |
| User entered '08:57' | (b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4) | 05 Feb 2021 18:55:43 |

US3232056

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Vital Signs Date and Time (derived)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:20:58 |
| User entered '05 Feb 2021 08:57' | (b) (4), (b) (6) System | 05 Feb 2021 18:55:43 |

US3232056

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Height (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:20:58 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 18 Mar 2021 15:26:53 |
| User entered '155' cm | (b) (4), (b) (6) Jerrica Sullivan (b) (4) | 05 Feb 2021 18:55:43 |
| DataPoint set to visible. | (b) (4) System | 05 Feb 2021 18:54:53 |

US3232056

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Weight (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:20:58 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 18 Mar 2021 15:26:53 |
| User entered '52.6' kg | (b) (4), (b) (6) Jerrica Sullivan (b) (4) | 05 Feb 2021 18:55:43 |
| DataPoint set to visible. | (b) (4) System | 05 Feb 2021 18:54:53 |

US3232056

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:20:58 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 18 Mar 2021 15:26:53 |
| User entered '98.5' F | (b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4) | 05 Feb 2021 18:55:43 |

US3232056

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:20:58 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 18 Mar 2021 15:26:53 |
| User entered 'Oral (Oral)' | (b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4) | 05 Feb 2021 18:55:43 |

US3232056

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:20:58 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 18 Mar 2021 15:26:53 |
| User entered empty. | (b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4) | 05 Feb 2021 18:55:43 |

US3232056

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:20:58 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 18 Mar 2021 15:26:53 |
| User entered '71' | (b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4) | 05 Feb 2021 18:55:43 |

US3232056

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:20:58 |
| User entered 'bpm' | (b) (4), (b) (6) System | 05 Feb 2021 18:55:43 |

US3232056

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:20:58 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 18 Mar 2021 15:26:53 |
| User entered '18' | (b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4) | 05 Feb 2021 18:55:43 |

US3232056

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:20:58 |
| User entered 'breaths/min' | (b) (4), (b) (6) System | 05 Feb 2021 18:55:43 |

US3232056

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:20:58 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 18 Mar 2021 15:26:53 |
| User entered '107' | (b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4) | 05 Feb 2021 18:55:43 |

US3232056

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:20:58 |
| User entered 'mmHg' | (b) (4), (b) (6) System | 05 Feb 2021 18:55:43 |

US3232056

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:20:58 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 18 Mar 2021 15:26:53 |
| User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6) | 09 Feb 2021 10:07:37 |
| Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs' (Site from System). | Jerrica Sullivan (b) (4) (b) (4) | 08 Feb 2021 21:00:12 |
| User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | | 05 Feb 2021 18:55:43 |
| User entered '58' | Jerrica Sullivan (b) (4) (b) (4) | 05 Feb 2021 18:55:43 |

US3232056

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:20:58 |
| User entered 'mmHg' | (b) (4), (b) (6) System | 05 Feb 2021 18:55:43 |

US3232056

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:20:58 |
| | (b) (4), (b) (6) | |

US3232056

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:52

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:20:58 |
| | (b) (4), (b) (6) | |

US3232056

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:52

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:20:53 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 18 Mar 2021 15:27:01 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4) | 05 Feb 2021 18:55:00 |

US3232056

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:52

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:20:53 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Mar 2021 15:27:01 |
| | (b) (4), (b) (6) | |
| User entered '05 Feb 2021' | Jerrica Sullivan (b) (4) | 05 Feb 2021 18:55:00 |
| | (b) (4) | |

US3232056

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:05:52

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:20:49 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 18 Mar 2021 15:27:09 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4) | 05 Feb 2021 18:55:57 |

US3232056

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:05:52

[Date of Collection](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:20:49 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Mar 2021 15:27:09 |
| | (b) (4), (b) (6) | |
| User entered '05 Feb 2021' | Jerrica Sullivan (b) (4) | 05 Feb 2021 18:55:57 |
| | (b) (4) | |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:52

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 11 Feb 2021 16:16:30 |
| | (b) (4) | |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:52

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '11 Feb 2021' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 11 Feb 2021 16:16:30 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:52

Was visit performed at the participant's home or at the clinic?

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Clinic (Clinic)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 11 Feb 2021 16:16:30 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:52

[Folder OID](#)

| Audit | User | Time (GMT) |
|------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User entered 'UNBLND_DECIDE' | (b) (4), (b) (6) System | 11 Feb 2021 16:16:30 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:05:52

Date of updated informed consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '11 Feb 2021' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 11 Feb 2021 16:17:16 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:05:52

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

| Audit | User | Time (GMT) |
|--------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 08 Mar 2021 21:55:22 |
| | (b) (4) | |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 12:51:51 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:05:52

[Was the participant unblinded?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Yes (Y)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 11 Feb 2021 16:17:16 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:05:52

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Amendment 6 or later (Amendment 6 or later)' | Jerrica Sullivan (b) (4) | 08 Mar 2021 21:55:22 |
| | (b) (4) | |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 12:51:51 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:05:52

Date of unblinding (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '11 Feb 2021' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 11 Feb 2021 16:17:16 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:05:52

[Participant randomization assignment](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Placebo (Placebo)' | Adreanna Pou (b) (4) | 11 Feb 2021 16:17:16 |
| | (b) (4) | |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:05:52

[Actual Dose 1](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Placebo (Placebo)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 11 Feb 2021 16:17:16 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:05:52

[Actual Dose 2](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Placebo (Placebo)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 11 Feb 2021 16:17:16 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:05:52

[Will participant receive mRNA-1273?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Yes (Y)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 11 Feb 2021 16:17:16 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:05:52

[Placebo Only Flag](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User entered '1' | (b) (4), (b) (6) System | 11 Feb 2021 16:17:16 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:05:52

[Continuing with mRNA-1273](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User entered 'I' | (b) (4), (b) (6) System | 11 Feb 2021 16:17:16 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:52

Height

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '156.5' cm | (b) (4) Adreanna Pou (b) (4) (b) (4) | 11 Feb 2021 16:19:58 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:52

[Weight](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '57.5' kg | Adreanna Pou (b) (4) | 11 Feb 2021 16:19:58 |
| | (b) (4) | |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:52

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User entered '23.47681' | System | 11 Feb 2021 16:19:58 |
| DataPoint set to visible. | System | 11 Feb 2021 16:17:16 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:52

Height

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '156.5' cm | (b) (4) Adreanna Pou (b) (4) (b) (4) | 11 Feb 2021 16:19:58 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:52

Weight

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '57.5' kg | Adreanna Pou (b) (4) | 11 Feb 2021 16:19:58 |
| | (b) (4) | |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:52

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User entered '23.47681' | System | 11 Feb 2021 16:19:58 |
| DataPoint set to visible. | System | 11 Feb 2021 16:17:16 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

[Timepoint](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------|-----------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User accepted default value 'Pre-Dose (PREDOSE)' | (b) (4), (b) (6) Adreanna Pou (b) (4) (b) (4) | 11 Feb 2021 16:19:58 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Yes (Y)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 11 Feb 2021 16:19:58 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '11 Feb 2021' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 11 Feb 2021 16:19:58 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '09:11' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 11 Feb 2021 16:19:58 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User entered '11 Feb 2021 09:11' | (b) (4), (b) (6) System | 11 Feb 2021 16:19:58 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '98.0' F | Adreanna Pou (b) (4) | 11 Feb 2021 16:19:58 |
| | (b) (4) | |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Oral (Oral)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 11 Feb 2021 16:19:58 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 11 Feb 2021 16:19:58 |
| | (b) (4) | |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '68' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 11 Feb 2021 16:19:58 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User entered 'bpm' | (b) (4), (b) (6) System | 11 Feb 2021 16:19:58 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '20' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 11 Feb 2021 16:19:58 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User entered 'breaths/min' | (b) (4), (b) (6) System | 11 Feb 2021 16:19:58 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '133' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 11 Feb 2021 16:19:58 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User entered 'mmHg' | (b) (4), (b) (6) System | 11 Feb 2021 16:19:58 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '72' | Adreanna Pou (b) (4) | 11 Feb 2021 16:19:58 |
| | (b) (4) | |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User entered 'mmHg' | (b) (4), (b) (6) System | 11 Feb 2021 16:19:58 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:52

Height

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '156.5' cm | (b) (4) Adreanna Pou (b) (4) (b) (4) | 11 Feb 2021 16:19:58 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:52

[Weight](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '57.5' kg | (b) (4) Adreanna Pou (b) (4) (b) (4) | 11 Feb 2021 16:19:58 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:52

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User entered '23.47681' | System | 11 Feb 2021 16:19:58 |
| DataPoint set to visible. | System | 11 Feb 2021 16:17:16 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

[Timepoint](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------|-----------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User accepted default value 'Post-Dose (POSTDOSE)' | (b) (4), (b) (6) Adreanna Pou (b) (4) (b) (4) | 11 Feb 2021 16:19:58 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Yes (Y)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 11 Feb 2021 16:19:58 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '11 Feb 2021' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 11 Feb 2021 16:19:58 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '09:50' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 11 Feb 2021 16:19:58 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User entered '11 Feb 2021 09:50' | (b) (4), (b) (6) System | 11 Feb 2021 16:19:58 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '97.2' F | Adreanna Pou (b) (4) | 11 Feb 2021 16:19:58 |
| | (b) (4) | |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

[Route of measurement](#)

| Audit | User | Time (GMT) |
|------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Other (Other)' | Adreanna Pou (b) (4) | 11 Feb 2021 16:19:58 |
| | (b) (4) | |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'temporal' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 11 Feb 2021 16:19:58 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '69' | Adreanna Pou (b) (4) | 11 Feb 2021 16:19:58 |
| | (b) (4) | |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User entered 'bpm' | (b) (4), (b) (6) System | 11 Feb 2021 16:19:58 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '20' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 11 Feb 2021 16:19:58 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User entered 'breaths/min' | (b) (4), (b) (6) System | 11 Feb 2021 16:19:58 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '128' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 11 Feb 2021 16:19:58 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User entered 'mmHg' | (b) (4), (b) (6) System | 11 Feb 2021 16:19:58 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '70' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 11 Feb 2021 16:19:58 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User entered 'mmHg' | (b) (4), (b) (6) System | 11 Feb 2021 16:19:58 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:52

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Yes (Y)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 11 Feb 2021 16:20:06 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:52

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '11 Feb 2021' | Adreanna Pou (b) (4) | 11 Feb 2021 16:20:06 |
| | (b) (4) | |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:52

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Yes (Y)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 11 Feb 2021 16:20:38 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:52

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Adreanna Pou (b) (4) (b) (4) | 11 Feb 2021 16:20:38 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:52

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) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Adreanna Pou (b) (4) (b) (4) | 11 Feb 2021 16:20:38 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:52

[What was the study treatment? \(Unblinded\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User entered 'mRNA-1273' | System | 11 Feb 2021 16:20:38 |
| DataPoint set to visible. | System | 11 Feb 2021 16:17:16 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:52

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '11 Feb 2021' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 11 Feb 2021 16:20:38 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:52

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '09:42' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 11 Feb 2021 16:20:38 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:52

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User entered '11 Feb 2021 09:42' | (b) (4), (b) (6) System | 11 Feb 2021 16:20:38 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:52

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 11 Feb 2021 16:20:38 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:52

What was the frequency of the study treatment dosing?

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User entered 'ONCE' | (b) (4), (b) (6) System | 11 Feb 2021 16:20:38 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:52

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User entered 'INTRAMUSCULAR' | (b) (4), (b) (6) System | 11 Feb 2021 16:20:38 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:52

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Yes (Y)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 11 Feb 2021 16:17:35 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:52

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '11 Feb 2021' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 11 Feb 2021 16:17:35 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:52

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '09:15' | Adreanna Pou (b) (4) | 11 Feb 2021 16:17:35 |
| | (b) (4) | |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:52

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User entered '11 Feb 2021 09:15' | (b) (4), (b) (6) System | 11 Feb 2021 16:17:35 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:05:52

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Yes (Y)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 11 Feb 2021 16:18:02 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:05:52

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '11 Feb 2021' | Adreanna Pou (b) (4) | 11 Feb 2021 16:18:02 |
| | (b) (4) | |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:05:52

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '09:12' | Adreanna Pou (b) (4) | 11 Feb 2021 16:18:02 |
| | (b) (4) | |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:05:52

[Collection Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User entered '11 Feb 2021 09:12' | (b) (4), (b) (6) System | 11 Feb 2021 16:18:02 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:52

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Yes (Y)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 11 Feb 2021 16:20:52 |

US3232056

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:52

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User entered 'I' | (b) (4), (b) (6) System | 11 Feb 2021 16:20:52 |

US3232056

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:42:12 |
| User entered 'Yes (Y)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Feb 2021 19:02:46 |

US3232056

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:42:12 |
| User closed query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | (b) (4) System | 18 Feb 2021 18:37:23 |
| Query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System). | System | 18 Feb 2021 18:37:23 |
| User closed query 'The 'Date of Contact or Contact Attempt' is before the 'Date of updated Informed Consent'. Please review and reconcile.' (Site from System). | System | 18 Feb 2021 18:37:23 |
| User entered '18 Feb 2021' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) (b) (4) | 18 Feb 2021 18:37:23 |
| Amendment Manager: User opened query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | System | 17 Feb 2021 00:56:45 |
| Amendment Manager: User opened query 'The 'Date of Contact or Contact Attempt' is before the 'Date of updated Informed Consent'. Please review and reconcile.' (Site from System). | System | 17 Feb 2021 00:56:45 |
| User entered '22 Jan 2021' | Jerrica Sullivan (b) (4) (b) (4) | 12 Feb 2021 19:02:46 |

US3232056

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:42:12 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Feb 2021 19:02:46 |

US3232056

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:42:12 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Feb 2021 19:02:46 |

US3232056

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:52

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:42:12 |
| User entered 'Yes (Y)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Feb 2021 19:02:57 |

US3232056

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:52

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User entered 'I' | (b) (4), (b) (6) System | 12 Feb 2021 19:02:57 |

US3232056

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:52

[OLD29 Placebo Flag](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User entered '1' | System | 12 Feb 2021 19:02:57 |
| DataPoint set to visible. | System | 12 Feb 2021 19:02:57 |

US3232056

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:52

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Adreanna Pou (b) (4) | 11 Mar 2021 15:25:01 |
| | (b) (4) | |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 19 Feb 2021 14:01:00 |
| | (b) (4), (b) (6) | |
| Query 'Data is required. Please complete.' answered with 'entered in error' (Site from System). | Jerrica Sullivan (b) (4) | 18 Feb 2021 18:34:28 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 18 Feb 2021 18:34:04 |
| User entered empty; reason for change Data Entry Error | Jerrica Sullivan (b) (4) | 18 Feb 2021 18:34:04 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 12 Feb 2021 19:03:09 |
| | (b) (4) | |

US3232056

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:52

Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '11 Mar 2021' reason for change: Data Entry Error | (b) (4) Adreanna Pou (b) (4) | 11 Mar 2021 15:25:01 |
| User closed query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System). | (b) (4) System | 18 Feb 2021 18:34:04 |
| Query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' answered by data change (Site from System). | System | 18 Feb 2021 18:34:04 |
| User entered empty; reason for change Data Entry Error | Jerrica Sullivan (b) (4) (b) (4) | 18 Feb 2021 18:34:04 |
| Amendment Manager: User opened query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System). | System | 17 Feb 2021 00:56:45 |
| User entered '12 Feb 2021' | Jerrica Sullivan (b) (4) (b) (4) | 12 Feb 2021 19:03:09 |

US3232056

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:52

Was visit performed at the participant's home or at the clinic?

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Clinic (Clinic)' reason for change: Data Entry Error | Adreanna Pou (b) (4) | 11 Mar 2021 15:25:01 |
| | (b) (4) | |
| User entered empty; reason for change Data Entry Error | Jerrica Sullivan (b) (4) | 18 Feb 2021 18:34:04 |
| | (b) (4) | |
| User entered 'Clinic (Clinic)' | Jerrica Sullivan (b) (4) | 12 Feb 2021 19:03:09 |
| | (b) (4) | |

US3232056

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:52

[Folder OID](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User entered 'OLD29' | System | 11 Mar 2021 15:25:01 |
| User entered empty. | System | 18 Feb 2021 18:34:04 |
| User entered 'OLD29' | System | 12 Feb 2021 19:03:09 |

US3232056

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

[Timepoint](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User accepted default value 'Pre-Dose (PREDOSE)' | Jerrica Sullivan (b) (4) | 12 Feb 2021 19:05:06 |
| | (b) (4) | |

US3232056

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4) Adreanna Pou (b) (4) | 11 Mar 2021 15:30:12 |
| User closed query 'Per CDM: Response noted. However Post dose vitals are recorded. Please review and update accordingly. Else clarify' (Site from DM). | (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) | 23 Feb 2021 10:16:25 |
| Query 'Per CDM: Response noted. However Post dose vitals are recorded. Please review and update accordingly. Else clarify' answered with 'error' (Site from DM). | Jerrica Sullivan (b) (4) (b) (4) | 22 Feb 2021 21:33:46 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) (b) (4), (b) (6) | 19 Feb 2021 14:00:51 |
| User opened query 'Per CDM: Response noted. However Post dose vitals are recorded. Please review and update accordingly. Else clarify' (Site from DM). | (b) (4), (b) (6) (b) (4), (b) (6) | 19 Feb 2021 14:00:07 |
| Query 'Data is required. Please complete.' answered with 'entered in error' (Site from System). | Jerrica Sullivan (b) (4) (b) (4) | 18 Feb 2021 18:35:24 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 18 Feb 2021 18:35:16 |
| User entered empty; reason for change Data Entry Error | Jerrica Sullivan (b) (4) (b) (4) | 18 Feb 2021 18:35:16 |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) (b) (4) | 12 Feb 2021 19:05:06 |

US3232056

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '11 Mar 2021' reason for change: Data Entry Error | Adreanna Pou (b) (4) | 11 Mar 2021 15:30:12 |
| | (b) (4) | |
| User entered empty; reason for change Data Entry Error | Jerrica Sullivan (b) (4) | 18 Feb 2021 18:35:16 |
| | (b) (4) | |
| User entered '12 Feb 2021' | Jerrica Sullivan (b) (4) | 12 Feb 2021 19:05:06 |
| | (b) (4) | |

US3232056

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|----------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '08:13' reason for change: Data Entry Error | Adreanna Pou (b) (4) | 11 Mar 2021 15:30:12 |
| | (b) (4) | |
| User entered empty; reason for change Data Entry Error | Jerrica Sullivan (b) (4) | 18 Feb 2021 18:35:16 |
| | (b) (4) | |
| User entered '11:06' | Jerrica Sullivan (b) (4) | 12 Feb 2021 19:05:06 |
| | (b) (4) | |

US3232056

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User entered '11 Mar 2021 08:13' | System | 11 Mar 2021 15:30:12 |
| User entered empty. | System | 18 Feb 2021 18:35:16 |
| User entered '12 Feb 2021 11:06' | System | 12 Feb 2021 19:05:06 |

US3232056

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '98.1' F reason for change: Data Entry Error | Adreanna Pou (b) (4) | 11 Mar 2021 15:30:12 |
| | (b) (4) | |
| User entered empty; reason for change Data Entry Error | Jerrica Sullivan (b) (4) | 18 Feb 2021 18:35:16 |
| | (b) (4) | |
| User entered '98.9' F | Jerrica Sullivan (b) (4) | 12 Feb 2021 19:05:06 |
| | (b) (4) | |

US3232056

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Oral (Oral)' reason for change: Data Entry Error | Adreanna Pou (b) (4) | 11 Mar 2021 15:30:12 |
| | (b) (4) | |
| User entered empty; reason for change Data Entry Error | Jerrica Sullivan (b) (4) | 18 Feb 2021 18:35:16 |
| | (b) (4) | |
| User entered 'Oral (Oral)' | Jerrica Sullivan (b) (4) | 12 Feb 2021 19:05:06 |
| | (b) (4) | |

US3232056

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 12 Feb 2021 19:05:06 |
| | (b) (4) | |

US3232056

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '65' reason for change: Data Entry Error | Adreanna Pou (b) (4) | 11 Mar 2021 15:30:12 |
| | (b) (4) | |
| User entered empty; reason for change Data Entry Error | Jerrica Sullivan (b) (4) | 18 Feb 2021 18:35:16 |
| | (b) (4) | |
| User entered '60' | Jerrica Sullivan (b) (4) | 12 Feb 2021 19:05:06 |
| | (b) (4) | |

US3232056

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User entered 'bpm' | System | 11 Mar 2021 15:30:12 |
| User entered empty. | System | 18 Feb 2021 18:35:16 |
| User entered 'bpm' | System | 12 Feb 2021 19:05:06 |

US3232056

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '18' reason for change: Data Entry Error | Adreanna Pou (b) (4) | 11 Mar 2021 15:30:12 |
| | (b) (4) | |
| User entered empty; reason for change Data Entry Error | Jerrica Sullivan (b) (4) | 18 Feb 2021 18:35:16 |
| | (b) (4) | |
| User entered '20' | Jerrica Sullivan (b) (4) | 12 Feb 2021 19:05:06 |
| | (b) (4) | |

US3232056

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User entered 'breaths/min' | System | 11 Mar 2021 15:30:12 |
| User entered empty. | System | 18 Feb 2021 18:35:16 |
| User entered 'breaths/min' | System | 12 Feb 2021 19:05:06 |

US3232056

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '122' reason for change: Data Entry Error | Adreanna Pou (b) (4) | 11 Mar 2021 15:30:12 |
| | (b) (4) | |
| User entered empty; reason for change Data Entry Error | Jerrica Sullivan (b) (4) | 18 Feb 2021 18:35:16 |
| | (b) (4) | |
| User entered '94' | Jerrica Sullivan (b) (4) | 12 Feb 2021 19:05:06 |
| | (b) (4) | |

US3232056

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User entered 'mmHg' | System | 11 Mar 2021 15:30:12 |
| User entered empty. | System | 18 Feb 2021 18:35:16 |
| User entered 'mmHg' | System | 12 Feb 2021 19:05:06 |

US3232056

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) | 12 Mar 2021 09:46:41 |
| Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs' (Site from System). | Adreanna Pou (b) (4) (b) (4) | 11 Mar 2021 15:30:33 |
| User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | | 11 Mar 2021 15:30:12 |
| User entered '59' reason for change: Data Entry Error | Adreanna Pou (b) (4) (b) (4) | 11 Mar 2021 15:30:12 |
| User entered empty; reason for change Data Entry Error | Jerrica Sullivan (b) (4) (b) (4) | 18 Feb 2021 18:35:16 |
| User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | (b) (4), (b) (6) (b) (4), (b) (6) | 15 Feb 2021 09:37:50 |
| Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs' (Site from System). | Jerrica Sullivan (b) (4) (b) (4) | 12 Feb 2021 19:15:21 |
| User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | | 12 Feb 2021 19:05:06 |
| User entered '48' | Jerrica Sullivan (b) (4) (b) (4) | 12 Feb 2021 19:05:06 |

US3232056

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:52

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User entered 'mmHg' | System | 11 Mar 2021 15:30:12 |
| User entered empty. | System | 18 Feb 2021 18:35:16 |
| User entered 'mmHg' | System | 12 Feb 2021 19:05:06 |

US3232056

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

[Timepoint](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User accepted default value 'Post-Dose (POSTDOSE)' | Jerrica Sullivan (b) (4) | 12 Feb 2021 19:05:06 |
| | (b) (4) | |

US3232056

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

Were vital signs assessed?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Adreanna Pou (b) (4) | 11 Mar 2021 15:30:12 |
| | (b) (4) | |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 23 Feb 2021 10:16:15 |
| | (b) (4), (b) (6) | |
| Query 'Data is required. Please complete.' answered with 'error' (Site from System). | Jerrica Sullivan (b) (4) | 22 Feb 2021 21:33:35 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 22 Feb 2021 21:33:30 |
| User entered empty; reason for change Data Entry Error | Jerrica Sullivan (b) (4) | 22 Feb 2021 21:33:30 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 12 Feb 2021 19:05:06 |
| | (b) (4) | |

US3232056

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '11 Mar 2021' reason for change: Data Entry Error | Adreanna Pou (b) (4) | 11 Mar 2021 15:30:12 |
| | (b) (4) | |
| User entered empty; reason for change Data Entry Error | Jerrica Sullivan (b) (4) | 22 Feb 2021 21:33:30 |
| | (b) (4) | |
| User entered '12 Feb 2021' | Jerrica Sullivan (b) (4) | 12 Feb 2021 19:05:06 |
| | (b) (4) | |

US3232056

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|----------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '09:18' reason for change: Data Entry Error | Adreanna Pou (b) (4) | 11 Mar 2021 15:30:12 |
| | (b) (4) | |
| User entered empty; reason for change Data Entry Error | Jerrica Sullivan (b) (4) | 22 Feb 2021 21:33:30 |
| | (b) (4) | |
| User entered '11:45' | Jerrica Sullivan (b) (4) | 12 Feb 2021 19:05:06 |
| | (b) (4) | |

US3232056

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User entered '11 Mar 2021 09:18' | System | 11 Mar 2021 15:30:12 |
| User entered empty. | System | 22 Feb 2021 21:33:30 |
| User entered '12 Feb 2021 11:45' | System | 12 Feb 2021 19:05:06 |

US3232056

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '98.6' F reason for change: Data Entry Error | Adreanna Pou (b) (4) | 11 Mar 2021 15:30:12 |
| | (b) (4) | |
| User entered empty; reason for change Data Entry Error | Jerrica Sullivan (b) (4) | 22 Feb 2021 21:33:30 |
| | (b) (4) | |
| User entered '98.7' F | Jerrica Sullivan (b) (4) | 12 Feb 2021 19:05:06 |
| | (b) (4) | |

US3232056

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

[Route of measurement](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Other (Other)' reason for change: Data Entry Error | Adreanna Pou (b) (4) | 11 Mar 2021 15:30:12 |
| | (b) (4) | |
| User entered empty; reason for change Data Entry Error | Jerrica Sullivan (b) (4) | 22 Feb 2021 21:33:30 |
| | (b) (4) | |
| User entered 'Other (Other)' | Jerrica Sullivan (b) (4) | 12 Feb 2021 19:05:06 |
| | (b) (4) | |

US3232056

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

[If Other, specify](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'temporal' reason for change: Data Entry Error | Adreanna Pou (b) (4) | 11 Mar 2021 15:30:12 |
| | (b) (4) | |
| User entered empty; reason for change Data Entry Error | Jerrica Sullivan (b) (4) | 22 Feb 2021 21:33:30 |
| | (b) (4) | |
| User entered 'temporal' | Jerrica Sullivan (b) (4) | 12 Feb 2021 19:05:06 |
| | (b) (4) | |

US3232056

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '62' reason for change: Data Entry Error | Adreanna Pou (b) (4) | 11 Mar 2021 15:30:12 |
| | (b) (4) | |
| User entered empty; reason for change Data Entry Error | Jerrica Sullivan (b) (4) | 22 Feb 2021 21:33:30 |
| | (b) (4) | |
| User entered '72' | Jerrica Sullivan (b) (4) | 12 Feb 2021 19:05:06 |
| | (b) (4) | |

US3232056

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User entered 'bpm' | System | 11 Mar 2021 15:30:12 |
| User entered empty. | System | 22 Feb 2021 21:33:30 |
| User entered 'bpm' | System | 12 Feb 2021 19:05:06 |

US3232056

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '18' reason for change: Data Entry Error | Adreanna Pou (b) (4) | 11 Mar 2021 15:30:12 |
| | (b) (4) | |
| User entered empty; reason for change Data Entry Error | Jerrica Sullivan (b) (4) | 22 Feb 2021 21:33:30 |
| | (b) (4) | |
| User entered '18' | Jerrica Sullivan (b) (4) | 12 Feb 2021 19:05:06 |
| | (b) (4) | |

US3232056

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User entered 'breaths/min' | System | 11 Mar 2021 15:30:12 |
| User entered empty. | System | 22 Feb 2021 21:33:30 |
| User entered 'breaths/min' | System | 12 Feb 2021 19:05:06 |

US3232056

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '130' reason for change: Data Entry Error | Adreanna Pou (b) (4) | 11 Mar 2021 15:30:12 |
| | (b) (4) | |
| User entered empty; reason for change Data Entry Error | Jerrica Sullivan (b) (4) | 22 Feb 2021 21:33:30 |
| | (b) (4) | |
| User entered '98' | Jerrica Sullivan (b) (4) | 12 Feb 2021 19:05:06 |
| | (b) (4) | |

US3232056

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User entered 'mmHg' | System | 11 Mar 2021 15:30:12 |
| User entered empty. | System | 22 Feb 2021 21:33:30 |
| User entered 'mmHg' | System | 12 Feb 2021 19:05:06 |

US3232056

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '60' reason for change: Data Entry Error | (b) (4) Adreanna Pou (b) (4) | 11 Mar 2021 15:30:12 |
| User entered empty; reason for change Data Entry Error | (b) (4) Jerrica Sullivan (b) (4) | 22 Feb 2021 21:33:30 |
| User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | (b) (4), (b) (6) (b) (4), (b) (6) | 15 Feb 2021 09:37:57 |
| Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs' (Site from System). | Jerrica Sullivan (b) (4) (b) (4) | 12 Feb 2021 19:15:28 |
| User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | | 12 Feb 2021 19:05:06 |
| User entered '56' | Jerrica Sullivan (b) (4) (b) (4) | 12 Feb 2021 19:05:06 |

US3232056

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:52

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User entered 'mmHg' | System | 11 Mar 2021 15:30:12 |
| User entered empty. | System | 22 Feb 2021 21:33:30 |
| User entered 'mmHg' | System | 12 Feb 2021 19:05:06 |

US3232056

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:52

Was the physical examination performed?

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 19 Feb 2021 14:01:06 |
| | (b) (4), (b) (6) | |
| Query 'Data is required. Please complete.' answered with 'entered in error' (Site from System). | Jerrica Sullivan (b) (4) | 18 Feb 2021 18:35:46 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 18 Feb 2021 18:35:37 |
| User entered empty; reason for change Data Entry Error | Jerrica Sullivan (b) (4) | 18 Feb 2021 18:35:37 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 12 Feb 2021 19:03:19 |
| | (b) (4) | |

US3232056

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:52

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty; reason for change Data Entry Error | Jerrica Sullivan (b) (4) | 18 Feb 2021 18:35:37 |
| | (b) (4) | |
| User entered '12 Feb 2021' | Jerrica Sullivan (b) (4) | 12 Feb 2021 19:03:19 |
| | (b) (4) | |

US3232056

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:52

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Adreanna Pou (b) (4) | 11 Mar 2021 15:31:11 |
| | (b) (4) | |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 19 Feb 2021 14:01:13 |
| | (b) (4), (b) (6) | |
| Query 'Data is required. Please complete.' answered with 'entered in error' (Site from System). | Jerrica Sullivan (b) (4) | 18 Feb 2021 18:36:06 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 18 Feb 2021 18:36:02 |
| User entered empty; reason for change Data Entry Error | Jerrica Sullivan (b) (4) | 18 Feb 2021 18:36:02 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 12 Feb 2021 19:04:04 |
| | (b) (4) | |

US3232056

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:52

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 12 Feb 2021 19:04:04 |
| | (b) (4) | |

US3232056

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:52

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) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Feb 2021 19:04:04 |

US3232056

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:52

[What was the study treatment? \(Unblinded\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User entered 'mRNA-1273' | System | 11 Mar 2021 15:31:11 |
| User entered empty. | System | 18 Feb 2021 18:36:02 |
| User entered 'mRNA-1273' | System | 12 Feb 2021 19:04:04 |
| DataPoint set to visible. | System | 12 Feb 2021 19:02:57 |

US3232056

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:52

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '11 Mar 2021' reason for change: Data Entry Error | Adreanna Pou (b) (4) | 11 Mar 2021 15:31:11 |
| | (b) (4) | |
| User entered empty; reason for change Data Entry Error | Jerrica Sullivan (b) (4) | 18 Feb 2021 18:36:02 |
| | (b) (4) | |
| User entered '12 Feb 2021' | Jerrica Sullivan (b) (4) | 12 Feb 2021 19:04:04 |
| | (b) (4) | |

US3232056

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:52

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '08:48' reason for change: Data Entry Error | Adreanna Pou (b) (4) | 11 Mar 2021 15:31:11 |
| | (b) (4) | |
| User entered empty; reason for change Data Entry Error | Jerrica Sullivan (b) (4) | 18 Feb 2021 18:36:02 |
| | (b) (4) | |
| User entered '11:30' | Jerrica Sullivan (b) (4) | 12 Feb 2021 19:04:04 |
| | (b) (4) | |

US3232056

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:52

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User entered '11 Mar 2021 08:48' | System | 11 Mar 2021 15:31:11 |
| User entered empty. | System | 18 Feb 2021 18:36:02 |
| User entered '12 Feb 2021 11:30' | System | 12 Feb 2021 19:04:04 |

US3232056

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:52

Which arm was used to give treatment?

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error | (b) (4) Adreanna Pou (b) (4) | 11 Mar 2021 15:31:11 |
| User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System). | (b) (4) System | 18 Feb 2021 18:36:02 |
| Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered by data change (Site from System). | System | 18 Feb 2021 18:36:02 |
| User entered empty; reason for change Data Entry Error | Jerrica Sullivan (b) (4) (b) (4) | 18 Feb 2021 18:36:02 |
| Amendment Manager: User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System). | System | 17 Feb 2021 00:56:45 |
| User entered 'Right Arm (RIGHT ARM)' | Jerrica Sullivan (b) (4) (b) (4) | 12 Feb 2021 19:04:04 |

US3232056

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:52

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User entered 'ONCE' | System | 11 Mar 2021 15:31:11 |
| User entered empty. | System | 18 Feb 2021 18:36:02 |
| User entered 'ONCE' | System | 12 Feb 2021 19:04:04 |

US3232056

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:52

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User entered 'INTRAMUSCULAR' | System | 11 Mar 2021 15:31:11 |
| User entered empty. | System | 18 Feb 2021 18:36:02 |
| User entered 'INTRAMUSCULAR' | System | 12 Feb 2021 19:04:04 |

US3232056

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:52

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 12 Feb 2021 19:03:13 |
| | (b) (4) | |

US3232056

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:52

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User entered 'I' | (b) (4), (b) (6) System | 12 Feb 2021 19:03:13 |

US3232056

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:42:12 |
| | (b) (4) | |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Adreanna Pou (b) (4) | 18 Mar 2021 19:30:44 |
| | (b) (4) | |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 19 Feb 2021 15:10:26 |
| | (b) (4), (b) (6) | |
| Query 'Data is required. Please complete.' answered with 'entered in error' (Site from System). | Jerrica Sullivan (b) (4) | 18 Feb 2021 18:37:10 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 18 Feb 2021 18:37:06 |
| User entered empty; reason for change Data Entry Error | Jerrica Sullivan (b) (4) | 18 Feb 2021 18:37:06 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 18 Feb 2021 18:30:03 |
| | (b) (4) | |

US3232056

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:42:12 |
| User entered '18 Mar 2021' reason for change: Data Entry Error | (b) (4) Adreanna Pou (b) (4) | 18 Mar 2021 19:30:44 |
| User entered empty; reason for change Data Entry Error | (b) (4) Jerrica Sullivan (b) (4) | 18 Feb 2021 18:37:06 |
| User closed query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | (b) (4) System | 18 Feb 2021 18:36:02 |
| Query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System). | System | 18 Feb 2021 18:36:02 |
| User opened query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | System | 18 Feb 2021 18:30:03 |
| User entered '18 Feb 2021' | Jerrica Sullivan (b) (4) (b) (4) | 18 Feb 2021 18:30:03 |

US3232056

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:42:12 |
| | (b) (4) | |
| User entered 'Contact Made (CONTACT MADE)' | Adreanna Pou (b) (4) | 18 Mar 2021 19:30:44 |
| reason for change: Data Entry Error | (b) (4) | |
| User entered empty; reason for change Data Entry Error | Jerrica Sullivan (b) (4) | 18 Feb 2021 18:37:06 |
| | (b) (4) | |
| User entered 'Contact Made (CONTACT MADE)' | Jerrica Sullivan (b) (4) | 18 Feb 2021 18:30:03 |
| | (b) (4) | |

US3232056

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:52

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:42:12 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 18 Feb 2021 18:30:03 |

US3232056

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:52

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:42:12 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 18 Mar 2021 19:30:49 |
| | (b) (4) | |

US3232056

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:52

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:10:50 |
| User entered 'I' | (b) (4), (b) (6) System | 18 Mar 2021 19:30:49 |

US3232056

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:05:52

Did the participant experience any adverse events?

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | ay 2021 10:34:45 |
| User closed query 'Per CDM: Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, FATIGUE lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' (Site from DM). | (b) (4), (b) (6) | 21 Apr 2021 09:13:06 |
| Query 'Per CDM: Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, FATIGUE lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' answered with 'updated ae log ' (Site from DM). | Jerrica Sullivan (b) (4) | 20 Apr 2021 17:24:13 |
| User opened query 'Per CDM: Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, FATIGUE lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' (Site from DM). | (b) (4), (b) (6) | 19 Apr 2021 05:40:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:41 |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:04:37 |

US3232056

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:52

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:37 |
| | (b) (4), (b) (6) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:52

[Adverse event](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:37 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) | 12 Mar 2021 19:53:10 |
| User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Sinusitis, LLT: Pansinusitis - version MedDRA\23.0. | Rambod Rouhbakhsh | 12 Nov 2020 15:03:47 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | (b) (4) | 12 Nov 2020 15:03:47 |
| Data point term sent to Coder | Coder Import (b) (4) | 12 Nov 2020 14:48:02 |
| Coding entries removed. | (b) (4) | 12 Nov 2020 14:47:31 |
| User entered 'pansinusitis' reason for change: Data Entry Error | Adreanna Pou (b) (4) | 12 Nov 2020 14:47:31 |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Paranasal sinus disorders (excl infections and neoplasms), PT: Sinus congestion, LLT: Sinus congestion - version MedDRA\23.0. | (b) (4) | 14 Oct 2020 14:50:35 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) | 14 Oct 2020 14:50:35 |
| Data point term sent to Coder | (b) (4) | 14 Oct 2020 14:50:02 |
| User closed query 'For coding purposes, please enter the type of CONGESTION [Nasal Congestion or Sinus Congestion or Respiratory Tract Congestion, lung congestion, etc] in order that the term may be coded accurately. please make your changes to the reported term.' (Site from System). | System | 14 Oct 2020 14:49:21 |
| Query 'For coding purposes, please enter the type of CONGESTION [Nasal Congestion or Sinus Congestion or Respiratory Tract Congestion, lung congestion, etc] in order that the term may be coded accurately. please make your changes to the reported term.' answered with 'corrected ' (Site from System). | Jerrica Sullivan (b) (4) | 14 Oct 2020 14:49:21 |
| User entered 'sinus CONGESTION' reason for change: Data Entry Error | (b) (4) | 14 Oct 2020 14:49:12 |

US3232056

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:52

[Adverse event](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User opened query 'For coding purposes, please enter the type of CONGESTION [Nasal Congestion or Sinus Congestion or Respiratory Tract Congestion, lung congestion, etc] in order that the term may be coded accurately. please make your changes to the reported term.' (Site from System). | Coder Import (b) (4) | 06 Oct 2020 22:47:22 |
| Data point term sent to Coder | System | 05 Oct 2020 22:05:55 |
| User entered 'congestion' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:05:27 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:52

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:37 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) | 12 Mar 2021 19:53:10 |
| User entered 'Yes (Y)' | Rambod Rouhbakhsh | 05 Oct 2020 22:05:27 |
| | (b) (4) | |
| | Jerrica Sullivan (b) (4) | |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:52

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:37 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:05:27 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:37 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) | 12 Mar 2021 19:53:10 |
| User entered 'No (N)' | Rambod Rouhbakhsh | 05 Oct 2020 22:05:27 |
| | (b) (4) | |
| | Jerrica Sullivan | |
| | (b) (4) | |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:52

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:37 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) | 12 Mar 2021 19:53:10 |
| User entered '30 Sep 2020' | Rambod Rouhbakhsh | 05 Oct 2020 22:05:27 |
| | (b) (4) | |
| | Jerrica Sullivan (b) (4) | |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:52

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:37 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:05:27 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:52

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:37 |
| User entered empty. | (b) (4), (b) (6) System | 05 Oct 2020 22:05:27 |

US3232056

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:37 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:05:27 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:37 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered '03 Oct 2020' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:05:27 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:52

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:37 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:05:27 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:52

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:37 |
| User entered empty. | (b) (4), (b) (6) System | 05 Oct 2020 22:05:27 |

US3232056

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:52

[Severity](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:37 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:05:27 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:52

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:37 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:05:27 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:52

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:37 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:05:27 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:52

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:37 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:05:27 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:52

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:37 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:05:27 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:52

Hospital Admission Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:37 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:05:27 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:52

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:37 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:05:27 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:52

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:37 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:05:27 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:52

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:37 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:05:27 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:52

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:37 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:05:27 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:52

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:37 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:05:27 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:52

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:37 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:05:27 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:52

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:37 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) | 12 Mar 2021 19:53:10 |
| User closed query 'Data is required. Please complete.' (Site from System). | Rambod Rouhbakhsh | 14 Oct 2020 14:49:12 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | (b) (4) | 14 Oct 2020 14:49:12 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | System | 14 Oct 2020 14:49:12 |
| User opened query 'Data is required. Please complete.' (Site from System). | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:05:27 |
| User entered empty. | (b) (4) | 05 Oct 2020 22:05:27 |

US3232056

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:52

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:37 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) | 12 Mar 2021 19:53:10 |
| User closed query 'Data is required. Please complete.' (Site from System). | Rambod Rouhbakhsh | 14 Oct 2020 14:49:12 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | (b) (4) | 14 Oct 2020 14:49:12 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | System | 14 Oct 2020 14:49:12 |
| User opened query 'Data is required. Please complete.' (Site from System). | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:05:27 |
| User entered empty. | (b) (4) | 05 Oct 2020 22:05:27 |

US3232056

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:52

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:37 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) | 12 Mar 2021 19:53:10 |
| User entered 'None (NONE)' | Rambod Rouhbakhsh | 05 Oct 2020 22:05:27 |
| | (b) (4) | |
| | Jerrica Sullivan (b) (4) | |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:52

None

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:37 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:05:27 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:52

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:37 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) | 12 Mar 2021 19:53:10 |
| User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM indication is PANSINUSITIS. Please confirm if this pertains to this AE. If yes, please review and reconcile AE term and CM indication, so there will be an appropriate match. Otherwise, review and add a Con Medication as appropriate or update action taken. | (b) (4) | 17 Nov 2020 16:35:03 |
| ' (Site from DM). | (b) (4), (b) (6) | |
| Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM indication is PANSINUSITIS. Please confirm if this pertains to this AE. If yes, please review and reconcile AE term and CM indication, so there will be an appropriate match. Otherwise, review and add a Con Medication as appropriate or update action taken. | Adreanna Pou (b) (4) | 12 Nov 2020 14:47:40 |
| ' answered with 'updated per query' (Site from DM). | (b) (4) | |
| User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM indication is PANSINUSITIS. Please confirm if this pertains to this AE. If yes, please review and reconcile AE term and CM indication, so there will be an appropriate match. Otherwise, review and add a Con Medication as appropriate or update action taken. | (b) (4), (b) (6) | 01 Nov 2020 02:31:30 |
| ' (Site from DM). | (b) (4), (b) (6) | |
| User entered 'I' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:05:27 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:52

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:37 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:05:27 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:52

[Outcome](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:37 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) | 12 Mar 2021 19:53:10 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Rambod Rouhbakhsh | 05 Oct 2020 22:05:27 |
| | (b) (4) | |
| | Jerrica Sullivan (b) (4) | |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:52

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:37 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:05:27 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:52

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:37 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:05:27 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:52

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:37 |
| User entered '0' | (b) (4), (b) (6) System | 05 Oct 2020 22:05:27 |

US3232056

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:52

Medically Attended AE Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:37 |
| User entered '1' | (b) (4), (b) (6) System | 05 Oct 2020 22:05:27 |

US3232056

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:52

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:37 |
| | (b) (4), (b) (6) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:52

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:46 |
| | (b) (4), (b) (6) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:52

[Adverse event](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:46 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) | 12 Mar 2021 19:53:10 |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Oropharyngeal pain, LLT: Sore throat - version MedDRA\\23.0. | Rambod Rouhbakhsh | 05 Oct 2020 22:07:27 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | (b) (4) | 05 Oct 2020 22:07:27 |
| Data point term sent to Coder | Coder Import (b) (4) | 05 Oct 2020 22:06:57 |
| User entered 'SOre THROAT' reason for change: | System | 05 Oct 2020 22:06:24 |
| Data Entry Error | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:06:11 |
| User entered 'soar throat' | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:52

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:46 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:06:11 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:52

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:46 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) | 12 Mar 2021 19:53:10 |
| User entered 'No (N)' | Rambod Rouhbakhsh | 05 Oct 2020 22:06:11 |
| | (b) (4) | |
| | Jerrica Sullivan (b) (4) | |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:46 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:06:11 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:52

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:46 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered '30 Sep 2020' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:06:11 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:52

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:46 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:06:11 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:52

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:46 |
| User entered empty. | (b) (4), (b) (6) System | 05 Oct 2020 22:06:11 |

US3232056

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:46 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:06:11 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:46 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered '03 Oct 2020' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:06:11 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:52

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:46 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:06:11 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:52

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:46 |
| User entered empty. | (b) (4), (b) (6) System | 05 Oct 2020 22:06:11 |

US3232056

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:52

[Severity](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:46 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:06:11 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:52

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:46 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:06:11 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:52

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:46 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:06:11 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:52

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:46 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:06:11 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:52

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:46 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:06:11 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:52

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:46 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:06:11 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:52

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:46 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:06:11 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:52

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:46 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:06:11 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:52

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:46 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:06:11 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:52

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:46 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:06:11 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:52

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:46 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:06:11 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:52

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:46 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:06:11 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:52

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:46 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) | 12 Mar 2021 19:53:10 |
| User closed query 'Data is required. Please complete.' (Site from System). | Rambod Rouhbakhsh | 14 Oct 2020 14:49:47 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | (b) (4) | 14 Oct 2020 14:49:47 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | System | 14 Oct 2020 14:49:47 |
| User opened query 'Data is required. Please complete.' (Site from System). | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:06:11 |
| User entered empty. | (b) (4) | 05 Oct 2020 22:06:11 |

US3232056

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:52

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:46 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 14 Oct 2020 14:49:47 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 14 Oct 2020 14:49:47 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) | 14 Oct 2020 14:49:47 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 05 Oct 2020 22:06:11 |
| User entered empty. | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:06:11 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:52

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:46 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered 'None (NONE)' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:06:11 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:52

None

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:46 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:06:11 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:52

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:46 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) | 12 Mar 2021 19:53:10 |
| User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. | (b) (4) | 01 Dec 2020 10:40:59 |
| ' (Site from DM). | (b) (4), (b) (6) | |
| Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. | Adreanna Pou (b) (4) | 12 Nov 2020 14:49:30 |
| ' answered with 'medication take for pansinusitis is also medication taken for sore throat' (Site from DM). | (b) (4) | |
| User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. | (b) (4), (b) (6) | 01 Nov 2020 02:31:46 |
| ' (Site from DM). | (b) (4), (b) (6) | |
| User entered 'I' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:06:11 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:52

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:46 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:06:11 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:52

[Outcome](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:46 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:06:11 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:52

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:46 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:06:11 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:52

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:46 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:06:11 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:52

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:46 |
| User entered '0' | (b) (4), (b) (6) System | 05 Oct 2020 22:06:11 |

US3232056

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:52

Medically Attended AE Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:02:46 |
| User entered '1' | (b) (4), (b) (6) System | 05 Oct 2020 22:06:11 |

US3232056

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:52

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) (b) (4), (b) (6) | 29 Apr 2021 13:02:46 |

US3232056

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:52

[AEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:47:52 |
| | (b) (4), (b) (6) | |
| User entered | System | 13 Jan 2021 17:47:33 |
| 'USA-US105-2021-mRNA-1273-P301000002' | | |
| User entered 'New' | (b) (4), (b) (6) | 13 Jan 2021 17:47:33 |
| | (b) (4), (b) (6) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:52

[Adverse event](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User closed query 'Per DM CLR: Please review the following AEs: #6 HEADACHE, & #7 COUGH as these have overlapping start/end dates. These are symptoms of COVID-19 Please review if these are related and combine these symptoms into one medical condition or diagnosis as appropriate. Otherwise, clarify.' (Site from DM). | (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) | 03 Mar 2021 10:16:40 |
| Query 'Per DM CLR: Please review the following AEs: #6 HEADACHE, & #7 COUGH as these have overlapping start/end dates. These are symptoms of COVID-19 Please review if these are related and combine these symptoms into one medical condition or diagnosis as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM). | Jerrica Sullivan (b) (4) (b) (4) | 02 Mar 2021 13:41:37 |
| User opened query 'Per DM CLR: Please review the following AEs: #6 HEADACHE, & #7 COUGH as these have overlapping start/end dates. These are symptoms of COVID-19 Please review if these are related and combine these symptoms into one medical condition or diagnosis as appropriate. Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) (b) (4), (b) (6) | 02 Mar 2021 02:40:18 |
| User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 12 Jan 2021 18:21:57 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 12 Jan 2021 18:21:57 |
| Data point term sent to Coder | System | 12 Jan 2021 18:20:48 |
| User entered 'COVID-19' | Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:20:13 |

US3232056

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:52

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User entered 'Yes (Y)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:20:13 |

US3232056

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:52

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the Solicited Adverse Reaction per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to "NO". Review and update as appropriate. Else, clarify. ' (Site from DM). | (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) | 09 Feb 2021 09:42:47 |
| Query 'Per DM CLR: Please review AE term reported as this is not included as one of the Solicited Adverse Reaction per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to "NO". Review and update as appropriate. Else, clarify. ' answered with 'updated' (Site from DM). | Jerrica Sullivan (b) (4) (b) (4) | 08 Feb 2021 14:20:06 |
| User entered 'No (N)' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) (b) (4) | 08 Feb 2021 14:19:59 |
| User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the Solicited Adverse Reaction per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to "NO". Review and update as appropriate. Else, clarify. ' (Site from DM). | (b) (4), (b) (6) (b) (4), (b) (6) | 24 Jan 2021 11:53:46 |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:20:13 |

US3232056

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User entered 'Yes (Y)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:20:13 |

US3232056

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:52

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User closed query 'PV Query: Per protocol, Onset date will be the date of onset of symptoms, or the date positive test was taken whichever is earlier. Please consider updating event start date to onset date of symptoms (02 Jan 2021). If not updating the start date, please clarify ' (Site from Safety). | (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) | 17 Feb 2021 21:40:53 |
| Query 'PV Query: Per protocol, Onset date will be the date of onset of symptoms, or the date positive test was taken whichever is earlier. Please consider updating event start date to onset date of symptoms (02 Jan 2021). If not updating the start date, please clarify ' answered with 'updated' (Site from Safety). | Jerrica Sullivan (b) (4) (b) (4) | 08 Feb 2021 14:20:52 |
| User entered '02 Jan 2021' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) (b) (4) | 08 Feb 2021 14:20:46 |
| User opened query 'PV Query: Per protocol, Onset date will be the date of onset of symptoms, or the date positive test was taken whichever is earlier. Please consider updating event start date to onset date of symptoms (02 Jan 2021). If not updating the start date, please clarify ' (Site from Safety). | (b) (4), (b) (6) (b) (4), (b) (6) | 21 Jan 2021 14:33:15 |
| User entered '08 Jan 2021' | Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:20:13 |

US3232056

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:52

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:20:13 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:52

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 12 Jan 2021 18:20:13 |

US3232056

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System). | System | 08 Feb 2021 14:20:46 |
| User entered 'No (N)' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) | 08 Feb 2021 14:20:46 |
| | (b) (4) | |
| User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System). | System | 05 Feb 2021 19:23:27 |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:20:13 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). | (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) | 17 Feb 2021 21:41:14 |
| Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety). | Jerrica Sullivan (b) (4) (b) (4) | 05 Feb 2021 19:23:38 |
| User entered '21 Jan 2021' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) (b) (4) | 05 Feb 2021 19:23:27 |
| User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). | (b) (4), (b) (6) (b) (4), (b) (6) | 21 Jan 2021 14:35:48 |
| User entered empty. | Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:20:13 |

US3232056

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:52

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:20:13 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:52

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 12 Jan 2021 18:20:13 |

US3232056

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:52

[Severity](#)

| Audit | User | Time (GMT) |
|------------------------------------------------|---------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | (b) (4) Jerrica Sullivan (b) (4) | 20 Jan 2021 22:14:34 |
| reason for change: Data Entry Error | (b) (4) | |
| User entered 'Grade 4 (Grade 4)' | Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:20:13 |

US3232056

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:52

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System). | (b) (4) System | 20 Jan 2021 22:14:34 |
| Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered by data change (Site from System). | System | 20 Jan 2021 22:14:34 |
| User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System). | System | 12 Jan 2021 18:20:13 |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:20:13 |

US3232056

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:52

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:20:13 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:52

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:20:13 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:52

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User entered '0' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:20:13 |

US3232056

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:52

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:20:13 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:52

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:20:13 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:52

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:20:13 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:52

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:20:13 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:52

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:20:13 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:52

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:20:13 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:52

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:20:13 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:52

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|------------------------------------------|------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User entered 'Not Related (NOT RELATED)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:20:13 |

US3232056

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:52

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|------------------------------------------|------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User entered 'Not Related (NOT RELATED)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:20:13 |

US3232056

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:52

Action taken with investigational product

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User closed query ' PV Query: As the last dose of study drug was given on 14 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety). | (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) | 17 Feb 2021 21:41:06 |
| Query ' PV Query: As the last dose of study drug was given on 14 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'updated' (Site from Safety). | Jerrica Sullivan (b) (4) (b) (4) | 08 Feb 2021 14:20:56 |
| User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) (b) (4) | 08 Feb 2021 14:20:46 |
| User opened query ' PV Query: As the last dose of study drug was given on 14 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety). | (b) (4), (b) (6) (b) (4), (b) (6) | 21 Jan 2021 14:34:45 |
| User entered 'None (NONE)' | Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:20:13 |

US3232056

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:52

None

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:20:13 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:52

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered 'I' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:20:13 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:52

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:20:13 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:52

[Outcome](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). | (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) | 17 Feb 2021 21:41:10 |
| Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety). | Jerrica Sullivan (b) (4) (b) (4) | 05 Feb 2021 19:23:52 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 05 Feb 2021 19:23:27 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 05 Feb 2021 19:23:27 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) (b) (4) | 05 Feb 2021 19:23:27 |
| User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). | (b) (4), (b) (6) (b) (4), (b) (6) | 21 Jan 2021 14:34:50 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 12 Jan 2021 18:20:13 |
| User entered empty. | Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:20:13 |

US3232056

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:52

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:20:13 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:52

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:20:13 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:52

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 12 Jan 2021 18:20:13 |

US3232056

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:05:52

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Jan 2021 18:20:13 |

US3232056

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:52

[AEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| Un-reviewed for Safety. | (b) (4), (b) (6) | 12 Feb 2021 20:38:13 |
| | (b) (4), (b) (6) | |
| User entered | (b) (4), (b) (6) | 12 Feb 2021 20:38:13 |
| 'USA-US105-2021-mRNA-1273-P301000002' | (b) (4), (b) (6) | |
| reason for change: Data Entry Error | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:16:34 |
| | (b) (4), (b) (6) | |
| User entered | System | 21 Jan 2021 14:16:16 |
| 'USA-US105-2021-mRNA-1273-P301000003' | | |
| User entered 'New' | (b) (4), (b) (6) | 21 Jan 2021 14:16:16 |
| | (b) (4), (b) (6) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:52

[Adverse event](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Disturbances in consciousness NEC, PT: Syncope, LLT: Syncope - version MedDRA\\23.0. | Coder Import (b) (4) | 20 Jan 2021 22:08:24 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 20 Jan 2021 22:08:24 |
| | (b) (4) | |
| Data point term sent to Coder | System | 20 Jan 2021 22:08:00 |
| User entered 'syncope' | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:07:40 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:52

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User entered 'Yes (Y)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 20 Jan 2021 22:07:40 |

US3232056

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:52

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User entered 'No (N)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 20 Jan 2021 22:07:40 |

US3232056

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User entered 'No (N)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 20 Jan 2021 22:07:40 |

US3232056

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:52

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered '16 Jan 2021' | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:07:40 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:52

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:07:40 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:52

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Jan 2021 22:07:40 |

US3232056

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:07:40 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User closed query 'Per DM CLR: Please review the dates of this AE as it is not expected that an episode of Syncope would have a duration of more than a single date. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' (Site from DM). | (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) | 23 Feb 2021 09:59:18 |
| Query 'Per DM CLR: Please review the dates of this AE as it is not expected that an episode of Syncope would have a duration of more than a single date. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' answered with 'confirm correct as entered' (Site from DM). | Jerrica Sullivan (b) (4) (b) (4) | 22 Feb 2021 21:32:27 |
| User opened query 'Per DM CLR: Please review the dates of this AE as it is not expected that an episode of Syncope would have a duration of more than a single date. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) (b) (4), (b) (6) | 16 Feb 2021 00:41:47 |
| User entered '19 Jan 2021' | Jerrica Sullivan (b) (4) (b) (4) | 20 Jan 2021 22:07:40 |

US3232056

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:52

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:07:40 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:52

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Jan 2021 22:07:40 |

US3232056

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:52

[Severity](#)

| Audit | User | Time (GMT) |
|------------------------------------------------|------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 20 Jan 2021 22:07:40 |

US3232056

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:52

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System). | (b) (4) System | 20 Jan 2021 22:07:59 |
| User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System). | System | 20 Jan 2021 22:07:40 |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) (b) (4) | 20 Jan 2021 22:07:40 |

US3232056

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:52

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:07:40 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:52

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User entered '0' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 20 Jan 2021 22:07:40 |

US3232056

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:52

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User closed query 'Requires inpatient or prolongation System of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). | (b) (4) | 20 Jan 2021 22:08:22 |
| Query 'Requires inpatient or prolongation of existing System Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System). | | 20 Jan 2021 22:08:22 |
| User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System). | | 20 Jan 2021 22:07:59 |
| Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System). | | 20 Jan 2021 22:07:59 |
| User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). | System | 20 Jan 2021 22:07:59 |
| User entered '1' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:07:59 |
| User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System). | (b) (4) System | 20 Jan 2021 22:07:40 |
| User entered '0' | Jerrica Sullivan (b) (4) (b) (4) | 20 Jan 2021 22:07:40 |

US3232056

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:52

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User entered '16 Jan 2021' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 20 Jan 2021 22:07:40 |

US3232056

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:52

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User entered '19 Jan 2021' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 20 Jan 2021 22:07:40 |

US3232056

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:52

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered 'No (N)' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:08:22 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:07:40 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:52

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:07:40 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:52

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:07:40 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:52

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:07:40 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:52

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:07:40 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:52

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|------------------------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered 'Not Related (NOT RELATED)' | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:07:40 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:52

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|------------------------------------------|------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User entered 'Not Related (NOT RELATED)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 20 Jan 2021 22:07:40 |

US3232056

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:52

Action taken with investigational product

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User closed query 'PV Query: As the last dose of study drug was given on 14 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety). | (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) | 23 Feb 2021 19:13:25 |
| Query 'PV Query: As the last dose of study drug was given on 14 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'updated' (Site from Safety). | Jerrica Sullivan (b) (4) (b) (4) | 22 Feb 2021 21:49:18 |
| User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) (b) (4) | 22 Feb 2021 21:49:13 |
| User opened query 'PV Query: As the last dose of study drug was given on 14 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety). | (b) (4), (b) (6) (b) (4), (b) (6) | 22 Feb 2021 20:51:45 |
| User entered 'None (NONE)' | Jerrica Sullivan (b) (4) (b) (4) | 20 Jan 2021 22:07:40 |

US3232056

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:52

None

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:07:40 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:52

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|----------------------------------------------------------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User closed query 'Per CDM: Please verify if CM# 24 'SODIUM CHLORIDE' (16-JAN-2021) is for indication 'SYNCOPE' in the Concomitant Medication eCRF? If yes, Please review and update Other Action Taken as appropriate.' (Site from DM). Query 'Per CDM: Please verify if CM# 24 'SODIUM CHLORIDE' (16-JAN-2021) is for indication 'SYNCOPE' in the Concomitant Medication eCRF? If yes, Please review and update Other Action Taken as appropriate.' answered with 'confirm #24 is for syncope' (Site from DM). | (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) | 12 Feb 2021 09:02:58 |
| User entered '1' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) (b) (4) | 11 Feb 2021 16:43:07 |
| User opened query 'Per CDM: Please verify if CM# 24 'SODIUM CHLORIDE' (16-JAN-2021) is for indication 'SYNCOPE' in the Concomitant Medication eCRF? If yes, Please review and update Other Action Taken as appropriate.' (Site from DM). User entered '0' | (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4) | 11 Feb 2021 16:42:51 11 Feb 2021 11:58:52 20 Jan 2021 22:07:40 |

US3232056

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:52

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 19 Mar 2021 14:05:37 |
| Signature has been broken. | (b) (4) Jerrica Sullivan (b) (4) | 15 Mar 2021 21:23:48 |
| User entered '0' reason for change: Data Entry Error | (b) (4) Jerrica Sullivan (b) (4) | 15 Mar 2021 21:23:48 |
| User signature succeeded. | (b) (4) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User closed query 'Per CDM- RQ: Please verify that no corresponding concomitant procedures recorded for this time frame, Please review and update appropriate details or "Uncheck the concomitant procedures box", else provide clarification.' (Site from DM). | (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) | 05 Mar 2021 11:40:44 |
| Query 'Per CDM- RQ: Please verify that no corresponding concomitant procedures recorded for this time frame, Please review and update appropriate details or "Uncheck the concomitant procedures box", else provide clarification.' answered with 'pacemaker was contributed to syncope, therefor con procedure needs to be checked ' (Site from DM). | Jerrica Sullivan (b) (4) (b) (4) | 04 Mar 2021 13:48:44 |
| User opened query 'Per CDM- RQ: Please verify that no corresponding concomitant procedures recorded for this time frame, Please review and update appropriate details or "Uncheck the concomitant procedures box", else provide clarification.' (Site from DM). | (b) (4), (b) (6) (b) (4), (b) (6) | 03 Mar 2021 11:09:03 |
| User closed query 'Per DM CLR: RQ: Response noted, however, 'medication line 24' is a drug therapy and not a procedure. Please review and update response as appropriate. Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) (b) (4), (b) (6) | 03 Mar 2021 11:09:03 |
| Query 'Per DM CLR: RQ: Response noted, however, 'medication line 24' is a drug therapy and not a procedure. Please review and update response as appropriate. Otherwise, clarify.' answered with 'confirm correct as entered' (Site from DM). | Jerrica Sullivan (b) (4) (b) (4) | 02 Mar 2021 16:24:35 |

US3232056

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:52

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------|
| User opened query 'Per DM CLR: RQ: Response noted, however, 'medication line 24' is a drug therapy and not a procedure. Please review and update response as appropriate. Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) (b) (4), (b) (6) | 02 Mar 2021 02:32:42 |
| User closed query 'Per CDM: Please verify if this pertains to CM# 24 'SODIUM CHLORIDE' (16-JAN-2021) for indication 'SYNCOPE' in the Concomitant Medication eCRF? If yes, Please review and update Other Action Taken as appropriate.' (Site from DM). | (b) (4), (b) (6) (b) (4), (b) (6) | 11 Feb 2021 11:56:44 |
| Query 'Per CDM: Please verify if this pertains to CM# 24 'SODIUM CHLORIDE' (16-JAN-2021) for indication 'SYNCOPE' in the Concomitant Medication eCRF? If yes, Please review and update Other Action Taken as appropriate.' answered with 'correct' (Site from DM). | Jerrica Sullivan (b) (4) (b) (4) | 09 Feb 2021 13:51:03 |
| User opened query 'Per CDM: Please verify if this pertains to CM# 24 'SODIUM CHLORIDE' (16-JAN-2021) for indication 'SYNCOPE' in the Concomitant Medication eCRF? If yes, Please review and update Other Action Taken as appropriate.' (Site from DM). | (b) (4), (b) (6) (b) (4), (b) (6) | 09 Feb 2021 09:49:42 |
| User closed query 'Per CDM: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic 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) (b) (4), (b) (6) | 09 Feb 2021 09:49:42 |
| Query 'Per CDM: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken' answered with 'medication line 24' (Site from DM). | Jerrica Sullivan (b) (4) (b) (4) | 08 Feb 2021 14:18:43 |

US3232056

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:52

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------|
| User opened query 'Per CDM: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic 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). User entered '1' | (b) (4), (b) (6) (b) (4), (b) (6) | 27 Jan 2021 11:08:06 |
| | Jerrica Sullivan (b) (4) (b) (4) | 20 Jan 2021 22:07:40 |

US3232056

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:52

[Outcome](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------|------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 20 Jan 2021 22:07:40 |

US3232056

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:52

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 20 Jan 2021 22:07:40 |

US3232056

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:52

[Narrative](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered 'Subject was admitted by ambulance to St Dominics Hospital in Jackson MS 16Jan2021 due to syncope related to intermittent complete heart block. While riding as a passenger in an automobile subject experienced intermittent altered conscious and syncope. The driver pulled over and summoned an ambulance. Patient had a PMH significant for cardiomyopathy and HTN was taking a beta blocker. Subject had a pacemaker placed on 18Jan2021 and was discharged on 19Jan2021. Subject had recent COVID infection 8Jan2021. Investigator does not think subject's syncope or heart block was related to IP since she had a known history of CHF/Cardiomyopathy and was taking a beta blocker' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) | 22 Jan 2021 17:41:28 |
| | (b) (4) | |
| User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System). | System | 20 Jan 2021 22:15:09 |
| Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System). | System | 20 Jan 2021 22:15:09 |
| User entered 'pacemaker placement on 18Jan2021' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:15:09 |
| | (b) (4) | |
| User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System). | System | 20 Jan 2021 22:07:40 |
| User entered empty. | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:07:40 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:52

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 20 Jan 2021 22:07:40 |

US3232056

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:52

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 20 Jan 2021 22:07:40 |

US3232056

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:05:52

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 20 Jan 2021 22:08:22 |

US3232056

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:52

[AEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Feb 2021 19:15:09 |
| | (b) (4), (b) (6) | |
| Un-reviewed for Safety. | (b) (4), (b) (6) | 12 Feb 2021 20:38:40 |
| | (b) (4), (b) (6) | |
| User entered | (b) (4), (b) (6) | 12 Feb 2021 20:38:40 |
| 'USA-US105-2021-mRNA-1273-P301000002' | (b) (4), (b) (6) | |
| reason for change: Data Entry Error | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:20 |
| | (b) (4), (b) (6) | |
| User entered | (b) (4), (b) (6) | 21 Jan 2021 14:17:11 |
| 'USA-US105-2021-mRNA-1273-P301000003' | (b) (4), (b) (6) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:52

[Adverse event](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Cardiac conduction disorders, PT: Atrioventricular block complete, LLT: Complete heart block - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) (b) (4) | 21 Jan 2021 00:13:12 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 21 Jan 2021 00:13:12 |
| Data point term sent to Coder | System | 20 Jan 2021 22:10:03 |
| User entered 'complete heart blockage' | Jerrica Sullivan (b) (4) (b) (4) | 20 Jan 2021 22:09:24 |

US3232056

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:52

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User entered 'Yes (Y)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 20 Jan 2021 22:09:24 |

US3232056

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:52

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User entered 'No (N)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 20 Jan 2021 22:09:24 |

US3232056

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User entered 'No (N)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 20 Jan 2021 22:09:24 |

US3232056

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:52

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered '16 Jan 2021' | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:09:24 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:52

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:09:24 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:52

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Jan 2021 22:09:24 |

US3232056

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User entered 'No (N)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 20 Jan 2021 22:09:24 |

US3232056

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, end date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User entered '19 Jan 2021' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 20 Jan 2021 22:09:24 |

US3232056

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:52

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:09:24 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:52

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Jan 2021 22:09:24 |

US3232056

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:52

[Severity](#)

| Audit | User | Time (GMT) |
|------------------------------------------------|------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 20 Jan 2021 22:09:24 |

US3232056

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:52

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User entered 'Yes (Y)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 20 Jan 2021 22:09:24 |

US3232056

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:52

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User entered '0' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 20 Jan 2021 22:09:24 |

US3232056

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:52

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User entered '0' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 20 Jan 2021 22:09:24 |

US3232056

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:52

Requires inpatient or prolongation of existing Hospitalization

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety). | (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) | 12 Feb 2021 18:54:36 |
| Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'records faxed' (Site from Safety). | Jerrica Sullivan (b) (4) (b) (4) | 12 Feb 2021 15:26:45 |
| User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety). | (b) (4), (b) (6) (b) (4), (b) (6) | 29 Jan 2021 18:27:43 |
| User entered 'I' | Jerrica Sullivan (b) (4) (b) (4) | 20 Jan 2021 22:09:24 |

US3232056

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:52

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered '16 Jan 2021' | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:09:24 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:52

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User entered '19 Jan 2021' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 20 Jan 2021 22:09:24 |

US3232056

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:52

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User entered 'No (N)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 20 Jan 2021 22:09:24 |

US3232056

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:52

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:09:24 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:52

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User entered '0' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 20 Jan 2021 22:09:24 |

US3232056

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:52

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:09:24 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:52

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User entered '0' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 20 Jan 2021 22:09:24 |

US3232056

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:52

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|------------------------------------------|------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User entered 'Not Related (NOT RELATED)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 20 Jan 2021 22:09:24 |

US3232056

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:52

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|------------------------------------------|------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User entered 'Not Related (NOT RELATED)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 20 Jan 2021 22:09:24 |

US3232056

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:52

Action taken with investigational product

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User closed query 'PV Query: As the last dose of study drug was given on 14 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety). | (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) | 12 Feb 2021 18:54:41 |
| Query 'PV Query: As the last dose of study drug was given on 14 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'updated' (Site from Safety). | Jerrica Sullivan (b) (4) (b) (4) | 11 Feb 2021 16:43:51 |
| User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) (b) (4) | 11 Feb 2021 16:43:39 |
| User opened query 'PV Query: As the last dose of study drug was given on 14 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety). | (b) (4), (b) (6) (b) (4), (b) (6) | 29 Jan 2021 18:27:31 |
| User entered 'None (NONE)' | Jerrica Sullivan (b) (4) (b) (4) | 20 Jan 2021 22:09:24 |

US3232056

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:52

None

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 19 Mar 2021 14:05:37 |
| Signature has been broken. | (b) (4) Jerrica Sullivan (b) (4) | 15 Mar 2021 21:24:06 |
| User entered '0' reason for change: Data Entry Error | (b) (4) Jerrica Sullivan (b) (4) | 15 Mar 2021 21:24:06 |
| User signature succeeded. | (b) (4) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Procedure (#1) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM). | (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) | 03 Mar 2021 11:10:08 |
| Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Procedure (#1) recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'confirm correct as entered' (Site from DM). | Jerrica Sullivan (b) (4) (b) (4) | 02 Mar 2021 16:24:25 |
| User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Procedure (#1) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM). | (b) (4), (b) (6) (b) (4), (b) (6) | 02 Mar 2021 02:33:02 |
| User entered '1' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) (b) (4) | 22 Feb 2021 21:48:32 |
| User entered '0' | Jerrica Sullivan (b) (4) (b) (4) | 20 Jan 2021 22:09:24 |

US3232056

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:52

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that is indicated for this AE. Please reconcile with ConMed page and update Indication of the corresponding medications given for this event. Please update as appropriate or provide clarification.' (Site from DM). | (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) | 23 Feb 2021 09:58:45 |
| Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that is indicated for this AE. Please reconcile with ConMed page and update Indication of the corresponding medications given for this event. Please update as appropriate or provide clarification.' answered with 'updated' (Site from DM). | Jerrica Sullivan (b) (4) (b) (4) | 22 Feb 2021 21:48:53 |
| User entered '0' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) | 22 Feb 2021 21:48:32 |
| User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that is indicated for this AE. Please reconcile with ConMed page and update Indication of the corresponding medications given for this event. Please update as appropriate or provide clarification.' (Site from DM). | (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) | 16 Feb 2021 00:41:33 |
| User entered '1' | Jerrica Sullivan (b) (4) (b) (4) | 20 Jan 2021 22:09:24 |

US3232056

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:52

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 19 Mar 2021 14:05:37 |
| Signature has been broken. | (b) (4) Jerrica Sullivan (b) (4) | 15 Mar 2021 21:24:06 |
| User entered '1' reason for change: Data Entry Error | (b) (4) Jerrica Sullivan (b) (4) | 15 Mar 2021 21:24:06 |
| User signature succeeded. | (b) (4) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User closed query 'Per CDM: Please review the Concomitant Procedures as there is corresponding CP (#1) recorded that matches this AE during this timeframe. Please review and update the CP check box, else provide clarification.' (Site from DM). | (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) | 05 Mar 2021 11:41:18 |
| Query 'Per CDM: Please review the Concomitant Procedures as there is corresponding CP (#1) recorded that matches this AE during this timeframe. Please review and update the CP check box, else provide clarification.' answered with 'pacemaker not directly contributed to heart blockage ' (Site from DM). | Jerrica Sullivan (b) (4) (b) (4) | 04 Mar 2021 13:49:06 |
| User opened query 'Per CDM: Please review the Concomitant Procedures as there is corresponding CP (#1) recorded that matches this AE during this timeframe. Please review and update the CP check box, else provide clarification.' (Site from DM). | (b) (4), (b) (6) (b) (4), (b) (6) | 03 Mar 2021 11:15:34 |
| User entered '0' | Jerrica Sullivan (b) (4) (b) (4) | 20 Jan 2021 22:09:24 |

US3232056

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:52

[Outcome](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------|------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 20 Jan 2021 22:09:24 |

US3232056

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:52

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User entered empty. | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 20 Jan 2021 22:09:24 |

US3232056

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:52

[Narrative](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:48 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 12 Mar 2021 19:53:10 |
| User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety). | (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) | 12 Feb 2021 18:54:51 |
| User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety). | (b) (4), (b) (6) (b) (4), (b) (6) | 12 Feb 2021 18:54:47 |
| User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). | (b) (4), (b) (6) (b) (4), (b) (6) | 12 Feb 2021 18:54:45 |
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Faxed 11Feb2021' (Site from Safety). | Jerrica Sullivan (b) (4) (b) (4) | 11 Feb 2021 17:26:02 |
| Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'Faxed 11Feb2021' (Site from Safety). | Jerrica Sullivan (b) (4) (b) (4) | 11 Feb 2021 17:25:50 |

US3232056

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:52

[Narrative](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------|
| Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'faxed 11Feb2021' (Site from Safety). | Jerrica Sullivan (b) (4) (b) (4) | 11 Feb 2021 17:25:38 |
| User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety). | (b) (4), (b) (6) (b) (4), (b) (6) | 29 Jan 2021 18:27:50 |
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety). | (b) (4), (b) (6) (b) (4), (b) (6) | 29 Jan 2021 18:27:22 |
| User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). | (b) (4), (b) (6) (b) (4), (b) (6) | 29 Jan 2021 18:27:16 |

US3232056

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:52

[Narrative](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|----------------------|
| User entered 'Subject was admitted by ambulance to St Dominics Hospital in Jackson MS 16Jan2021 due to syncope related to intermittent complete heart block. While riding as a passenger in an automobile subject experienced intermittent altered conscious and syncope. The driver pulled over and summoned an ambulance. Patient had a PMH significant for cardiomyopathy and HTN was taking a beta blocker. Subject had a pacemaker placed on 18Jan2021 and was discharged on 19jan2021. Subject had recent COVID infection 8Jan2021. Investigator does not think subject's syncope or heart block was related to IP since she had a known history of CHF/Cardiomyopathy and was taking a beta blocker' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) (b) (4) | 22 Jan 2021 17:41:06 |
| User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System). | System | 20 Jan 2021 22:15:41 |
| Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System). | System | 20 Jan 2021 22:15:41 |
| User entered 'awaiting medical records to record con med taken for heart blockage' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) (b) (4) | 20 Jan 2021 22:15:41 |
| User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System). | System | 20 Jan 2021 22:09:24 |
| User entered empty. | Jerrica Sullivan (b) (4) (b) (4) | 20 Jan 2021 22:09:24 |

US3232056

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:52

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Jan 2021 22:09:24 |

US3232056

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:52

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Jan 2021 22:09:24 |

US3232056

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:05:52

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 20 Jan 2021 22:09:24 |

US3232056

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:05:52

[Adverse event](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Sinusitis, LLT: Sinusitis - version MedDRA\\23.0. | Coder Import (b) (4) | 19 Apr 2021 21:55:35 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 19 Apr 2021 21:55:35 |
| | (b) (4) | |
| Data point term sent to Coder | System | 19 Apr 2021 21:54:28 |
| User entered 'SINUSITIS' | Adreanna Pou (b) (4) | 19 Apr 2021 21:53:39 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:05:52

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:53:39 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:05:52

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:53:39 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:05:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:53:39 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:05:52

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '09 Apr 2021' | Adreanna Pou (b) (4) | 19 Apr 2021 21:53:39 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:05:52

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 21:53:39 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:05:52

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Apr 2021 21:53:39 |

US3232056

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:53:39 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, end date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 21:53:39 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:05:52

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 21:53:39 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:05:52

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Apr 2021 21:53:39 |

US3232056

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:05:52

[Severity](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:53:39 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:05:52

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:53:39 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:05:52

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 21:53:39 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:05:52

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 21:53:39 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:05:52

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 21:53:39 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:05:52

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 21:53:39 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:05:52

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 21:53:39 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:05:52

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 21:53:39 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:05:52

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 21:53:39 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:05:52

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 21:53:39 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:05:52

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 21:53:39 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:05:52

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 21:53:39 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:05:52

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|------------------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Not Related (NOT RELATED)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:53:39 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:05:52

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|------------------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Not Related (NOT RELATED)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:53:39 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:05:52

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|------------------------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Not Applicable (NOT APPLICABLE)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:53:39 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:05:52

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 21:53:39 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:05:52

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'I' | Adreanna Pou (b) (4) | 19 Apr 2021 21:53:39 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:05:52

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 21:53:39 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:05:52

[Outcome](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:53:39 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:05:52

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 21:53:39 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:05:52

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 21:53:39 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:05:52

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 19 Apr 2021 21:53:39 |

US3232056

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:05:52

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 19 Apr 2021 21:53:39 |

US3232056

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:05:52

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:24 |
| | (b) (4), (b) (6) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:05:52

[Adverse event](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:24 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) (b) (4) | 19 Apr 2021 21:58:40 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 19 Apr 2021 21:58:40 |
| Data point term sent to Coder | System | 19 Apr 2021 21:57:37 |
| User entered 'FATIGUE' | Adreanna Pou (b) (4) (b) (4) | 19 Apr 2021 21:56:47 |

US3232056

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:05:52

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:24 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:56:47 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:05:52

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:24 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:56:47 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:05:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:24 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| User entered 'No (N)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 19 Apr 2021 21:56:47 |

US3232056

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:05:52

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:24 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '02 Apr 2021' | Adreanna Pou (b) (4) | 19 Apr 2021 21:56:47 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:05:52

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:24 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 21:56:47 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:05:52

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:24 |
| User entered empty. | (b) (4), (b) (6) System | 19 Apr 2021 21:56:47 |

US3232056

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:24 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:56:47 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, end date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:24 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '17 Apr 2021' | Adreanna Pou (b) (4) | 19 Apr 2021 21:56:47 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:05:52

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:24 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 21:56:47 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:05:52

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:24 |
| User entered empty. | (b) (4), (b) (6) System | 19 Apr 2021 21:56:47 |

US3232056

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:05:52

[Severity](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:24 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 19 Apr 2021 21:56:47 |

US3232056

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:05:52

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:24 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:56:47 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:05:52

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:24 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 21:56:47 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:05:52

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:24 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 21:56:47 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:05:52

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:24 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 21:56:47 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:05:52

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:24 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 21:56:47 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:05:52

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:24 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 21:56:47 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:05:52

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:24 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 21:56:47 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:05:52

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:24 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 21:56:47 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:05:52

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:24 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 21:56:47 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:05:52

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:24 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 21:56:47 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:05:52

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:24 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 21:56:47 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:05:52

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|------------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:24 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Not Related (NOT RELATED)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:56:47 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:05:52

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|------------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:24 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Not Related (NOT RELATED)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:56:47 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:05:52

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|------------------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:24 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Not Applicable (NOT APPLICABLE)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:56:47 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:05:52

None

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:24 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'I' | Adreanna Pou (b) (4) | 19 Apr 2021 21:56:47 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:05:52

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:24 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 21:56:47 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:05:52

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:24 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 21:56:47 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:05:52

[Outcome](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:24 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4) Adreanna Pou (b) (4) (b) (4) | 19 Apr 2021 21:56:47 |

US3232056

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:05:52

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:24 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 21:56:47 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:05:52

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:24 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 21:56:47 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:05:52

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:24 |
| User entered '0' | (b) (4), (b) (6) System | 19 Apr 2021 21:56:47 |

US3232056

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:05:52

Medically Attended AE Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:24 |
| User entered '0' | (b) (4), (b) (6) System | 19 Apr 2021 21:56:47 |

US3232056

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:05:52

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:24 |
| | (b) (4), (b) (6) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:05:52

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:32 |
| | (b) (4), (b) (6) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:05:52

[Adverse event](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:32 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0. | Coder Import (b) (4) | 19 Apr 2021 21:59:41 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 19 Apr 2021 21:59:41 |
| | (b) (4) | |
| Data point term sent to Coder | System | 19 Apr 2021 21:58:38 |
| User entered 'HEADACHE' | Adreanna Pou (b) (4) | 19 Apr 2021 21:57:56 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:05:52

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:32 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:57:56 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:05:52

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:32 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:57:56 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:05:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:32 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:57:56 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:05:52

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:32 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '11 Apr 2021' | Adreanna Pou (b) (4) | 19 Apr 2021 21:57:56 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:05:52

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:32 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 21:57:56 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:05:52

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:32 |
| User entered empty. | (b) (4), (b) (6) System | 19 Apr 2021 21:57:56 |

US3232056

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:32 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:57:56 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, end date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:32 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '17 Apr 2021' | Adreanna Pou (b) (4) | 19 Apr 2021 21:57:56 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:05:52

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:32 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 21:57:56 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:05:52

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:32 |
| User entered empty. | (b) (4), (b) (6) System | 19 Apr 2021 21:57:56 |

US3232056

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:05:52

[Severity](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:32 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:57:56 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:05:52

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:32 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:57:56 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:05:52

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:32 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 21:57:56 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:05:52

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:32 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 21:57:56 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:05:52

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:32 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 21:57:56 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:05:52

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:32 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 21:57:56 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:05:52

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:32 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 21:57:56 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:05:52

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:32 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 21:57:56 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:05:52

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:32 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 21:57:56 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:05:52

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:32 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 21:57:56 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:05:52

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:32 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 21:57:56 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:05:52

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:32 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 21:57:56 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:05:52

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|------------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:32 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Not Related (NOT RELATED)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:57:56 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:05:52

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|------------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:32 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Not Related (NOT RELATED)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:57:56 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:05:52

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|------------------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:32 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Not Applicable (NOT APPLICABLE)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:57:56 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:05:52

None

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:32 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 21:57:56 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:05:52

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:32 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'I' | Adreanna Pou (b) (4) | 19 Apr 2021 21:57:56 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:05:52

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:32 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 21:57:56 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:05:52

[Outcome](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:32 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 19 Apr 2021 21:58:08 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 19 Apr 2021 21:58:08 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: | Adreanna Pou (b) (4) | 19 Apr 2021 21:58:08 |
| Data Entry Error | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 19 Apr 2021 21:57:56 |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 21:57:56 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:05:52

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:32 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 21:57:56 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:05:52

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:32 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 21:57:56 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:05:52

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:32 |
| User entered '0' | (b) (4), (b) (6) System | 19 Apr 2021 21:57:56 |

US3232056

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:05:52

Medically Attended AE Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:32 |
| User entered '1' | (b) (4), (b) (6) System | 19 Apr 2021 21:57:56 |

US3232056

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:05:52

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:32 |
| | (b) (4), (b) (6) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:05:52

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:40 |
| | (b) (4), (b) (6) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:05:52

[Adverse event](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:40 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Nasal congestion, LLT: Nasal congestion - version MedDRA\\23.0. | Coder Import (b) (4) | 19 Apr 2021 22:01:39 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 19 Apr 2021 22:01:39 |
| | (b) (4) | |
| Data point term sent to Coder | System | 19 Apr 2021 22:00:44 |
| User entered 'NASAL CONGESTION' | Adreanna Pou (b) (4) | 19 Apr 2021 21:59:57 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:05:52

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:40 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:59:57 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:05:52

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:40 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:59:57 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:05:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:40 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:59:57 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:05:52

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:40 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '11 Apr 2021' | Adreanna Pou (b) (4) | 19 Apr 2021 21:59:57 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:05:52

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:40 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 21:59:57 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:05:52

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:40 |
| User entered empty. | (b) (4), (b) (6) System | 19 Apr 2021 21:59:57 |

US3232056

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:40 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:59:57 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, end date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:40 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '17 Apr 2021' | Adreanna Pou (b) (4) | 19 Apr 2021 21:59:57 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:05:52

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:40 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 21:59:57 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:05:52

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:40 |
| User entered empty. | (b) (4), (b) (6) System | 19 Apr 2021 21:59:57 |

US3232056

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:05:52

[Severity](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:40 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:59:57 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:05:52

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:40 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:59:57 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:05:52

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:40 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 21:59:57 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:05:52

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:40 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 21:59:57 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:05:52

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:40 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 21:59:57 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:05:52

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:40 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 21:59:57 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:05:52

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:40 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 21:59:57 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:05:52

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:40 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 21:59:57 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:05:52

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:40 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 21:59:57 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:05:52

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:40 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 21:59:57 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:05:52

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:40 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 21:59:57 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:05:52

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:40 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 21:59:57 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:05:52

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|------------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:40 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Not Related (NOT RELATED)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:59:57 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:05:52

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|------------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:40 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Not Related (NOT RELATED)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:59:57 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:05:52

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|------------------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:40 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Not Applicable (NOT APPLICABLE)' | Adreanna Pou (b) (4) | 19 Apr 2021 21:59:57 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:05:52

None

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:40 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 21:59:57 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:05:52

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:40 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'I' | Adreanna Pou (b) (4) | 19 Apr 2021 21:59:57 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:05:52

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:40 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 21:59:57 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:05:52

[Outcome](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:40 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 19 Apr 2021 22:00:04 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 19 Apr 2021 22:00:04 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: | Adreanna Pou (b) (4) | 19 Apr 2021 22:00:04 |
| Data Entry Error | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 19 Apr 2021 21:59:57 |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 21:59:57 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:05:52

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:40 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 21:59:57 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:05:52

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:40 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 21:59:57 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:05:52

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:40 |
| User entered '0' | (b) (4), (b) (6) System | 19 Apr 2021 21:59:57 |

US3232056

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:05:52

Medically Attended AE Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:40 |
| User entered '1' | (b) (4), (b) (6) System | 19 Apr 2021 21:59:57 |

US3232056

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:05:52

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:40 |
| | (b) (4), (b) (6) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:05:52

[Adverse event](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Ageusia, LLT: Loss of taste - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) | 20 Apr 2021 00:34:36 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 20 Apr 2021 00:34:36 |
| Data point term sent to Coder | System | 19 Apr 2021 22:10:55 |
| User entered 'LOST OF TASTE' | Adreanna Pou (b) (4) (b) (4) | 19 Apr 2021 22:10:46 |

US3232056

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:05:52

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 19 Apr 2021 22:10:46 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:05:52

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 19 Apr 2021 22:10:46 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:05:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 19 Apr 2021 22:10:46 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:05:52

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '19 Apr 2021' | Adreanna Pou (b) (4) | 19 Apr 2021 22:10:46 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:05:52

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 22:10:46 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:05:52

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Apr 2021 22:10:46 |

US3232056

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 19 Apr 2021 22:10:46 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, end date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 22:10:46 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:05:52

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 22:10:46 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:05:52

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Apr 2021 22:10:46 |

US3232056

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:05:52

[Severity](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Adreanna Pou (b) (4) | 19 Apr 2021 22:10:46 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:05:52

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 19 Apr 2021 22:10:46 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:05:52

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 22:10:46 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:05:52

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 22:10:46 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:05:52

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 22:10:46 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:05:52

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 22:10:46 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:05:52

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 22:10:46 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:05:52

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 22:10:46 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:05:52

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 22:10:46 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:05:52

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 22:10:46 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:05:52

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 22:10:46 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:05:52

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 22:10:46 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:05:52

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|------------------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Not Related (NOT RELATED)' | Adreanna Pou (b) (4) | 19 Apr 2021 22:10:46 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:05:52

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|------------------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Not Related (NOT RELATED)' | Adreanna Pou (b) (4) | 19 Apr 2021 22:10:46 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:05:52

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|------------------------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Not Applicable (NOT APPLICABLE)' | Adreanna Pou (b) (4) | 19 Apr 2021 22:10:46 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:05:52

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '1' | Adreanna Pou (b) (4) | 19 Apr 2021 22:10:46 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:05:52

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 22:10:46 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:05:52

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 22:10:46 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:05:52

[Outcome](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' | Adreanna Pou (b) (4) | 19 Apr 2021 22:10:46 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:05:52

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 22:10:46 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:05:52

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 22:10:46 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:05:52

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 19 Apr 2021 22:10:46 |

US3232056

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:05:52

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 19 Apr 2021 22:10:46 |

US3232056

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:05:52

[Adverse event](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User coded data point as SOC: Nervous system disorders, HLGT: Cranial nerve disorders (excl neoplasms), HLT: Olfactory nerve disorders, PT: Anosmia, LLT: Loss of smell - version MedDRA\\23.0. | Coder Import (b) (4) | 20 Apr 2021 00:34:35 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 20 Apr 2021 00:34:35 |
| | (b) (4) | |
| Data point term sent to Coder | System | 19 Apr 2021 22:11:56 |
| User entered 'lost of smell' | Adreanna Pou (b) (4) | 19 Apr 2021 22:11:28 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:05:52

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 19 Apr 2021 22:11:28 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:05:52

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 19 Apr 2021 22:11:28 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:05:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 19 Apr 2021 22:11:28 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:05:52

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '19 Apr 2021' | Adreanna Pou (b) (4) | 19 Apr 2021 22:11:28 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:05:52

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 22:11:28 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:05:52

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Apr 2021 22:11:28 |

US3232056

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 19 Apr 2021 22:11:28 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, end date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 22:11:28 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:05:52

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 22:11:28 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:05:52

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Apr 2021 22:11:28 |

US3232056

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:05:52

[Severity](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Adreanna Pou (b) (4) | 19 Apr 2021 22:11:28 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:05:52

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 19 Apr 2021 22:11:28 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:05:52

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 22:11:28 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:05:52

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 22:11:28 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:05:52

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 22:11:28 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:05:52

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 22:11:28 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:05:52

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 22:11:28 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:05:52

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 22:11:28 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:05:52

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 22:11:28 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:05:52

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 22:11:28 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:05:52

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 22:11:28 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:05:52

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 22:11:28 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:05:52

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|------------------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Not Related (NOT RELATED)' | Adreanna Pou (b) (4) | 19 Apr 2021 22:11:28 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:05:52

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|------------------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Not Related (NOT RELATED)' | Adreanna Pou (b) (4) | 19 Apr 2021 22:11:28 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:05:52

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|------------------------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Not Applicable (NOT APPLICABLE)' | Adreanna Pou (b) (4) | 19 Apr 2021 22:11:28 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:05:52

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '1' | Adreanna Pou (b) (4) | 19 Apr 2021 22:11:28 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:05:52

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 22:11:28 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:05:52

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 22:11:28 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:05:52

[Outcome](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' | Adreanna Pou (b) (4) | 19 Apr 2021 22:11:28 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:05:52

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 22:11:28 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:05:52

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 22:11:28 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:05:52

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 19 Apr 2021 22:11:28 |

US3232056

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:05:52

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 19 Apr 2021 22:11:28 |

US3232056

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:05:52

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:50 |
| | (b) (4), (b) (6) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:05:52

[Adverse event](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0. | Coder Import (b) (4) | 20 Apr 2021 17:17:39 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 20 Apr 2021 17:17:39 |
| | (b) (4) | |
| Data point term sent to Coder | System | 20 Apr 2021 17:17:00 |
| User entered 'FATIGUE' | Jerrica Sullivan (b) (4) | 20 Apr 2021 17:16:42 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:05:52

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 20 Apr 2021 17:16:42 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:05:52

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 20 Apr 2021 17:16:42 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:05:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 20 Apr 2021 17:16:42 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:05:52

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '23 Aug 2020' | Jerrica Sullivan (b) (4) | 20 Apr 2021 17:16:42 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:05:52

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| 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 | 20 Apr 2021 17:18:39 |
| User entered empty; reason for change Data Entry Error | Jerrica Sullivan (b) (4) | 20 Apr 2021 17:18:39 |
| | (b) (4) | |
| 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 | 20 Apr 2021 17:16:42 |
| User entered '21:42' | Jerrica Sullivan (b) (4) | 20 Apr 2021 17:16:42 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:05:52

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:50 |
| | (b) (4), (b) (6) | |
| User entered empty. | System | 20 Apr 2021 17:18:39 |
| User entered '23 Aug 2020 21:42' | System | 20 Apr 2021 17:16:42 |

US3232056

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 20 Apr 2021 17:16:42 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, end date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '28 Aug 2020' | Jerrica Sullivan (b) (4) | 20 Apr 2021 17:16:42 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:05:52

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System). | System | 20 Apr 2021 17:18:39 |
| User entered empty; reason for change Data Entry Error | Jerrica Sullivan (b) (4) | 20 Apr 2021 17:18:39 |
| | (b) (4) | |
| User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System). | System | 20 Apr 2021 17:16:42 |
| User entered '20:51' | Jerrica Sullivan (b) (4) | 20 Apr 2021 17:16:42 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:05:52

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:50 |
| | (b) (4), (b) (6) | |
| User entered empty. | System | 20 Apr 2021 17:18:39 |
| User entered '28 Aug 2020 20:51' | System | 20 Apr 2021 17:16:42 |

US3232056

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:05:52

[Severity](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|---------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | (b) (4) Jerrica Sullivan (b) (4) | 20 Apr 2021 17:16:42 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:05:52

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 20 Apr 2021 17:16:42 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:05:52

Death

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 20 Apr 2021 17:16:42 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:05:52

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 20 Apr 2021 17:16:42 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:05:52

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 20 Apr 2021 17:16:42 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:05:52

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 20 Apr 2021 17:16:42 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:05:52

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 20 Apr 2021 17:16:42 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:05:52

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 20 Apr 2021 17:16:42 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:05:52

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 20 Apr 2021 17:16:42 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:05:52

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 20 Apr 2021 17:16:42 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:05:52

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 20 Apr 2021 17:16:42 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:05:52

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 20 Apr 2021 17:16:42 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:05:52

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 20 Apr 2021 19:00:44 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 20 Apr 2021 19:00:44 |
| User entered 'Related (RELATED)' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) | 20 Apr 2021 19:00:44 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 20 Apr 2021 17:16:42 |
| User entered empty. | Jerrica Sullivan (b) (4) | 20 Apr 2021 17:16:42 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:05:52

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 20 Apr 2021 19:00:44 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 20 Apr 2021 19:00:44 |
| User entered 'Not Related (NOT RELATED)' | Jerrica Sullivan (b) (4) | 20 Apr 2021 19:00:44 |
| reason for change: Data Entry Error | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 20 Apr 2021 17:16:42 |
| User entered empty. | Jerrica Sullivan (b) (4) | 20 Apr 2021 17:16:42 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:05:52

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'None (NONE)' | Jerrica Sullivan (b) (4) | 20 Apr 2021 17:16:42 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:05:52

None

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'I' | Jerrica Sullivan (b) (4) | 20 Apr 2021 17:16:42 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:05:52

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 20 Apr 2021 17:16:42 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:05:52

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 20 Apr 2021 17:16:42 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:05:52

[Outcome](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------|------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:50 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4) Jerrica Sullivan (b) (4) (b) (4) | 20 Apr 2021 17:16:42 |

US3232056

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:05:52

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 20 Apr 2021 17:16:42 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:05:52

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 20 Apr 2021 17:16:42 |
| | (b) (4) | |

US3232056

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:05:52

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:50 |
| User entered '0' | (b) (4), (b) (6) System | 20 Apr 2021 17:16:42 |

US3232056

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:05:52

Medically Attended AE Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:50 |
| User entered '0' | (b) (4), (b) (6) System | 20 Apr 2021 17:16:42 |

US3232056

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:05:52

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:05:50 |
| | (b) (4), (b) (6) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:05:52

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | May 2021 10:34:45 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:45:58 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:52

Name of Medication

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|----------------------------------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) (b) (4) | 12 Nov 2020 14:55:48 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 12 Nov 2020 14:55:48 |
| Data point term sent to Coder Coding entries removed. | System Adreanna Pou (b) (4) (b) (4) | 12 Nov 2020 14:55:10 12 Nov 2020 14:54:37 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 18 Aug 2020 12:48:24 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 18 Aug 2020 12:48:24 |
| Data point term sent to Coder User entered 'lisinopril' | System Jerrica Sullivan (b) (4) (b) (4) | 18 Aug 2020 12:47:39 18 Aug 2020 12:46:53 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:52

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:46:53 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:52

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User closed query 'Per DM CLR: Please review and ensure that the Indication reflects a medical condition or diagnosis. Update eCRF as appropriate. (Site from DM). | (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) | 23 Nov 2020 15:36:30 |
| Query 'Per DM CLR: Please review and ensure that the Indication reflects a medical condition or diagnosis. Update eCRF as appropriate. ' answered with 'updated per query resolution' (Site from DM). | Adreanna Pou (b) (4) (b) (4) | 12 Nov 2020 14:54:57 |
| User entered 'hypertension' reason for change: Data Entry Error | Adreanna Pou (b) (4) (b) (4) | 12 Nov 2020 14:54:37 |
| User opened query 'Per DM CLR: Please review and ensure that the Indication reflects a medical condition or diagnosis. Update eCRF as appropriate. (Site from DM). | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Sep 2020 13:39:26 |
| User entered 'blood pressure' | Jerrica Sullivan (b) (4) (b) (4) | 18 Aug 2020 12:46:53 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:52

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '2.5' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:46:53 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:52

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'mg (mg)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:46:53 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:52

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:46:53 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:52

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:46:53 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:52

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:46:53 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:52

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:46:53 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:52

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:46:53 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:52

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '6 Aug 2020' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:46:53 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:52

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:46:53 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:46:53 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:46:53 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:52

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:46:53 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:52

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 18 Aug 2020 12:46:53 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 18 Aug 2020 12:46:53 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 18 Aug 2020 12:46:53 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:52

[Name of Medication](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------------------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 12 Nov 2020 15:13:53 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 12 Nov 2020 15:13:53 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 12 Nov 2020 14:57:49 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 12 Nov 2020 14:57:49 |
| Data point term sent to Coder Coding entries removed. | System Adreanna Pou (b) (4) | 12 Nov 2020 14:56:13 12 Nov 2020 14:55:34 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 26 Aug 2020 15:40:45 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 26 Aug 2020 15:40:45 |
| Data point term sent to Coder | System | 26 Aug 2020 15:39:25 |

PRODUCTION RELEASE (v12.003
EAB) (1725)

3547 of 4306

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:52

[Name of Medication](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| User entered 'aspirin' | Adreanna Pou (b) (4) (b) (4) | 26 Aug 2020 15:38:37 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:52

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User closed query 'Per CDM: it appears this medication was used for prophylaxis; however, it is not recorded as Prophylaxis. Please review, reconcile, and update accordingly.' (Site from DM). | (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) | 13 Oct 2020 09:38:43 |
| Query 'Per CDM: it appears this medication was used for prophylaxis; however, it is not recorded as Prophylaxis. Please review, reconcile, and update accordingly.' answered with 'corrected' (Site from DM). | Adreanna Pou (b) (4) (b) (4) | 08 Sep 2020 14:15:26 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Adreanna Pou (b) (4) (b) (4) | 08 Sep 2020 14:15:12 |
| User opened query 'Per CDM: it appears this medication was used for prophylaxis; however, it is not recorded as Prophylaxis. Please review, reconcile, and update accordingly.' (Site from DM). | (b) (4), (b) (6) (b) (4), (b) (6) | 05 Sep 2020 10:11:49 |
| User entered 'No (N)' | Adreanna Pou (b) (4) (b) (4) | 26 Aug 2020 15:38:37 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:52

[Indication](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication (e.g., NAUSEA prophylaxis) and ensure that the "prophylaxis" box is ticked. Update Con Med eCRF as appropriate. ' (Site from DM). | (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) | 20 Nov 2020 07:47:38 |
| Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication (e.g., NAUSEA prophylaxis) and ensure that the "prophylaxis" box is ticked. Update Con Med eCRF as appropriate. ' answered with 'updated per query resolution' (Site from DM). | Adreanna Pou (b) (4) (b) (4) | 12 Nov 2020 14:55:42 |
| User entered 'cardiac PROPHYLACTIC' reason for change: Data Entry Error | Adreanna Pou (b) (4) (b) (4) | 12 Nov 2020 14:55:34 |
| User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication (e.g., NAUSEA prophylaxis) and ensure that the "prophylaxis" box is ticked. Update Con Med eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Sep 2020 10:22:44 |
| User entered 'prophylactic' | Adreanna Pou (b) (4) (b) (4) | 26 Aug 2020 15:38:37 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:52

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '81' | Adreanna Pou (b) (4) | 26 Aug 2020 15:38:37 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:52

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'mg (mg)' | Adreanna Pou (b) (4) | 26 Aug 2020 15:38:37 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:52

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 15:38:37 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:52

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Adreanna Pou (b) (4) | 26 Aug 2020 15:38:37 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:52

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 15:38:37 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:52

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Adreanna Pou (b) (4) | 26 Aug 2020 15:38:37 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:52

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 15:38:37 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:52

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'un UNK 2019' | Adreanna Pou (b) (4) | 26 Aug 2020 15:38:37 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:52

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 26 Aug 2020 15:38:37 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 26 Aug 2020 15:38:37 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 15:38:37 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:52

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 26 Aug 2020 15:38:37 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:52

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 15:38:37 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 15:38:37 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 26 Aug 2020 15:38:37 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:52

[Name of Medication](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 26 Aug 2020 15:41:44 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 26 Aug 2020 15:41:44 |
| | (b) (4) | |
| Data point term sent to Coder | System | 26 Aug 2020 15:41:28 |
| User entered 'albuterol' | Adreanna Pou (b) (4) | 26 Aug 2020 15:40:43 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:52

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 26 Aug 2020 15:40:43 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:52

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'asthma' | Adreanna Pou (b) (4) | 26 Aug 2020 15:40:43 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:52

[Dose per administration](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User closed query 'Per DM CLR: Please review Dose if 108 is more appropriate and Dose Unit: ug. Please update all applicable details as appropriate.' (Site from DM). | (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) | 23 Nov 2020 15:39:47 |
| Query 'Per DM CLR: Please review Dose if 108 is more appropriate and Dose Unit: ug. Please update all applicable details as appropriate.' answered with 'corrected per query resolution' (Site from DM). | Adreanna Pou (b) (4) (b) (4) | 12 Nov 2020 15:06:29 |
| User entered '108' reason for change: Data Entry Error | Adreanna Pou (b) (4) (b) (4) | 12 Nov 2020 15:05:48 |
| User opened query 'Per DM CLR: Please review Dose if 108 is more appropriate and Dose Unit: ug. Please update all applicable details as appropriate.' (Site from DM). | (b) (4), (b) (6) (b) (4), (b) (6) | 05 Oct 2020 09:48:06 |
| Query 'Per DM CLR: Please review and remove one of the recorded doses as either is an acceptable dosage. Update eCRF as appropriate.' canceled (Site from DM). | (b) (4), (b) (6) (b) (4), (b) (6) | 05 Oct 2020 09:47:58 |
| Query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate.' canceled (Site from DM). | (b) (4), (b) (6) (b) (4), (b) (6) | 05 Oct 2020 09:47:56 |
| User opened query 'Per DM CLR: Please review and remove one of the recorded doses as either is an acceptable dosage. Update eCRF as appropriate.' (Site from DM). | (b) (4), (b) (6) (b) (4), (b) (6) | 15 Sep 2020 06:59:54 |
| User opened query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate.' (Site from DM). | (b) (4), (b) (6) (b) (4), (b) (6) | 15 Sep 2020 06:59:44 |
| User entered '108 (90)' | Adreanna Pou (b) (4) (b) (4) | 26 Aug 2020 15:40:43 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:52

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'ug (ug)' reason for change: Data Entry Error | Adreanna Pou (b) (4) | 12 Nov 2020 15:05:48 |
| | (b) (4) | |
| User entered 'mg (mg)' | Adreanna Pou (b) (4) | 26 Aug 2020 15:40:43 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:52

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 15:40:43 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:52

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'as needed (PRN)' | Adreanna Pou (b) (4) | 26 Aug 2020 15:40:43 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:52

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 15:40:43 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:52

[Route of administration](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' | Adreanna Pou (b) (4) | 26 Aug 2020 15:40:43 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:52

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 15:40:43 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:52

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'un UNK 2017' | Adreanna Pou (b) (4) | 26 Aug 2020 15:40:43 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:52

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 26 Aug 2020 15:40:43 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 26 Aug 2020 15:40:43 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 15:40:43 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:52

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User closed query 'Per CDM: medication taken for solicited event is recorded as 'Yes' however Adverse event page is blank. Please review and update accordingly else clarify. Thank you' (Site from DM). | (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) | 07 Sep 2020 09:07:14 |
| Query 'Per CDM: medication taken for solicited event is recorded as 'Yes' however Adverse event page is blank. Please review and update accordingly else clarify. Thank you' answered with 'corrected' (Site from DM). | Adreanna Pou (b) (4) (b) (4) | 02 Sep 2020 19:50:10 |
| User entered 'No (N)' reason for change: Data Entry Error | Adreanna Pou (b) (4) (b) (4) | 02 Sep 2020 19:49:57 |
| User opened query 'Per CDM: medication taken for solicited event is recorded as 'Yes' however Adverse event page is blank. Please review and update accordingly else clarify. Thank you' (Site from DM). | (b) (4), (b) (6) (b) (4), (b) (6) | 02 Sep 2020 12:56:45 |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) (b) (4) | 26 Aug 2020 15:40:43 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:52

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Aug 2020 15:40:43 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Aug 2020 15:40:43 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Aug 2020 15:40:43 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:52

Name of Medication

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE FUROATE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: BREO ELLIPTA - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 13 Nov 2020 00:24:40 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 13 Nov 2020 00:24:40 |
| | (b) (4) | |
| Data point term sent to Coder | System | 12 Nov 2020 15:26:56 |
| Coding entries removed. | Adreanna Pou (b) (4) | 12 Nov 2020 15:26:45 |
| | (b) (4) | |
| User entered 'BREO ELLIPTA 100/25' reason for change: Data Entry Error | Adreanna Pou (b) (4) | 12 Nov 2020 15:26:45 |
| | (b) (4) | |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE FUROATE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: BREO ELLIPTA - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 26 Aug 2020 15:45:46 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 26 Aug 2020 15:45:46 |
| | (b) (4) | |
| Data point term sent to Coder | System | 26 Aug 2020 15:44:33 |
| User entered 'breo ellipta' | Adreanna Pou (b) (4) | 26 Aug 2020 15:43:36 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:52

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 26 Aug 2020 15:43:36 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:52

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'asthma/ copd' | Adreanna Pou (b) (4) | 26 Aug 2020 15:43:36 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:52

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '1' reason for change: Data Entry Error | Adreanna Pou (b) (4) | 12 Nov 2020 15:26:45 |
| | (b) (4) | |
| Query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate. | (b) (4), (b) (6) | 15 Sep 2020 05:02:36 |
| ' canceled (Site from DM). | (b) (4), (b) (6) | |
| User opened query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate. | (b) (4), (b) (6) | 15 Sep 2020 05:02:28 |
| ' (Site from DM). | | |
| User entered '100-25' | Adreanna Pou (b) (4) | 26 Aug 2020 15:43:36 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:52

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User closed query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate. ' (Site from DM). | (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) | 23 Nov 2020 15:40:11 |
| Query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate. ' answered with 'updated per query resolution' (Site from DM). | Adreanna Pou (b) (4) (b) (4) | 12 Nov 2020 15:26:55 |
| User entered 'puff (PUFF)' reason for change: Data Entry Error | Adreanna Pou (b) (4) (b) (4) | 12 Nov 2020 15:26:45 |
| User opened query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate. ' (Site from DM). | (b) (4), (b) (6) (b) (4), (b) (6) | 15 Sep 2020 05:02:41 |
| User entered 'mg (mg)' | Adreanna Pou (b) (4) (b) (4) | 26 Aug 2020 15:43:36 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:52

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 15:43:36 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:52

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Adreanna Pou (b) (4) | 26 Aug 2020 15:43:36 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:52

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 15:43:36 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:52

[Route of administration](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' | Adreanna Pou (b) (4) | 26 Aug 2020 15:43:36 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:52

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 15:43:36 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:52

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'un UNK 2017' | Adreanna Pou (b) (4) | 26 Aug 2020 15:43:36 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:52

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 26 Aug 2020 15:43:36 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 26 Aug 2020 15:43:36 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 15:43:36 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:52

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 26 Aug 2020 15:43:36 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:52

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 15:43:36 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 15:43:36 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 26 Aug 2020 15:43:36 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:52

Name of Medication

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|----------------------------------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 12 Nov 2020 15:28:34 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 12 Nov 2020 15:28:34 |
| Data point term sent to Coder Coding entries removed. | System Adreanna Pou (b) (4) | 12 Nov 2020 15:27:57 12 Nov 2020 15:27:13 |
| | (b) (4) | |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 26 Aug 2020 15:49:48 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 26 Aug 2020 15:49:48 |
| Data point term sent to Coder User entered 'carvedilol' | System Adreanna Pou (b) (4) (b) (4) | 26 Aug 2020 15:48:38 26 Aug 2020 15:48:07 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:52

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 26 Aug 2020 15:48:07 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:52

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User closed query 'Per DM CLR: Please review and ensure that the Indication reflects a medical condition or diagnosis. Update eCRF as appropriate. (b) (4), (b) (6) | (b) (4), (b) (6) | 23 Nov 2020 15:40:53 |
| ' (Site from DM). | | |
| Query 'Per DM CLR: Please review and ensure that the Indication reflects a medical condition or diagnosis. Update eCRF as appropriate. (b) (4) | Adreanna Pou (b) (4) | 12 Nov 2020 15:27:21 |
| ' answered with 'updated per query resolution' (Site from DM). | (b) (4) | |
| User entered 'hypertension' reason for change: Data Entry Error | Adreanna Pou (b) (4) | 12 Nov 2020 15:27:13 |
| User opened query 'Per DM CLR: Please review and ensure that the Indication reflects a medical condition or diagnosis. Update eCRF as appropriate. (b) (4), (b) (6) | (b) (4), (b) (6) | 14 Sep 2020 13:39:55 |
| ' (Site from DM). | | |
| User entered 'blood pressure' | Adreanna Pou (b) (4) | 26 Aug 2020 15:48:07 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:52

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '12.5' | Adreanna Pou (b) (4) | 26 Aug 2020 15:48:07 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:52

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'mg (mg)' | Adreanna Pou (b) (4) | 26 Aug 2020 15:48:07 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:52

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 15:48:07 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:52

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Adreanna Pou (b) (4) | 26 Aug 2020 15:48:07 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:52

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 15:48:07 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:52

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Adreanna Pou (b) (4) | 26 Aug 2020 15:48:07 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:52

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 15:48:07 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:52

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'un UNK 2019' | Adreanna Pou (b) (4) | 26 Aug 2020 15:48:07 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:52

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 26 Aug 2020 15:48:07 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 26 Aug 2020 15:48:07 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 15:48:07 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:52

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 26 Aug 2020 15:48:07 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:52

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 15:48:07 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 15:48:07 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 26 Aug 2020 15:48:07 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:52

Name of Medication

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: DDD COLECALCIFEROL (VITAMIN D3) - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 12 Nov 2020 20:50:35 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 12 Nov 2020 20:50:35 |
| Data point term sent to Coder | System | 12 Nov 2020 15:18:43 |
| Coding entries removed. | Adreanna Pou (b) (4) (b) (4) | 12 Nov 2020 15:18:04 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 27 Aug 2020 17:43:35 |
| 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 Aug 2020 17:43:35 |
| Data point term sent to Coder | System | 26 Aug 2020 16:08:22 |
| User entered 'cholecalciferol (vitamin d3)' | Adreanna Pou (b) (4) (b) (4) | 26 Aug 2020 16:07:32 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:52

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User closed query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify.' (Site from DM). | (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) | 30 Dec 2020 09:00:12 |
| Query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM). | Jerrica Sullivan (b) (4) (b) (4) | 29 Dec 2020 13:19:22 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) (b) (4) | 29 Dec 2020 13:19:16 |
| User opened query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) (b) (4), (b) (6) | 24 Dec 2020 06:54:09 |
| User entered 'No (N)' | Adreanna Pou (b) (4) (b) (4) | 26 Aug 2020 16:07:32 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:52

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User closed query 'Per DM CLR: Please review and ensure that the Indication reflects a medical condition or diagnosis. Update eCRF as appropriate. (b) (4), (b) (6) | (b) (4), (b) (6) | 23 Nov 2020 15:41:50 |
| ' (Site from DM). | | |
| Query 'Per DM CLR: Please review and ensure that the Indication reflects a medical condition or diagnosis. Update eCRF as appropriate. (b) (4) | Adreanna Pou (b) (4) | 12 Nov 2020 15:27:37 |
| ' answered with 'updated per query resolution' (Site from DM). | (b) (4) | |
| User entered 'general health' reason for change: Data Entry Error | Adreanna Pou (b) (4) | 12 Nov 2020 15:18:04 |
| User opened query 'Per DM CLR: Please review and ensure that the Indication reflects a medical condition or diagnosis. Update eCRF as appropriate. (b) (4), (b) (6) | (b) (4), (b) (6) | 14 Sep 2020 14:31:44 |
| ' (Site from DM). | | |
| User entered 'cognitive' | Adreanna Pou (b) (4) | 26 Aug 2020 16:07:32 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:52

[Dose per administration](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User closed query ' Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM). | (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) | 23 Nov 2020 15:41:49 |
| Query ' Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'confirmed correct as entered. it is an over the counter drug and per patient response the exact dosage is unknown' (Site from DM). | Adreanna Pou (b) (4) (b) (4) | 12 Nov 2020 15:28:18 |
| User opened query ' Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Sep 2020 14:31:46 |
| User entered 'I' | Adreanna Pou (b) (4) (b) (4) | 26 Aug 2020 16:07:32 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:52

[Dose unit](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'tablet (TABLET)' | Adreanna Pou (b) (4) | 26 Aug 2020 16:07:32 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:52

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 16:07:32 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:52

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Adreanna Pou (b) (4) | 26 Aug 2020 16:07:32 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:52

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 16:07:32 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:52

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Adreanna Pou (b) (4) | 26 Aug 2020 16:07:32 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:52

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 16:07:32 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:52

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'un UNK 2019' | Adreanna Pou (b) (4) | 26 Aug 2020 16:07:32 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:52

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 26 Aug 2020 16:07:32 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 26 Aug 2020 16:07:32 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 16:07:32 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:52

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 26 Aug 2020 16:07:32 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:52

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 16:07:32 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 16:07:32 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 26 Aug 2020 16:07:32 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:52

[Name of Medication](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: FLUOXETINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 26 Aug 2020 18:35:16 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 26 Aug 2020 18:35:16 |
| | (b) (4) | |
| Data point term sent to Coder | System | 26 Aug 2020 16:09:27 |
| User entered 'fluoxetine' | Adreanna Pou (b) (4) | 26 Aug 2020 16:09:00 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:52

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 26 Aug 2020 16:09:00 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:52

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'anxiety' | Adreanna Pou (b) (4) | 26 Aug 2020 16:09:00 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:52

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '20' | Adreanna Pou (b) (4) | 26 Aug 2020 16:09:00 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:52

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'mg (mg)' | Adreanna Pou (b) (4) | 26 Aug 2020 16:09:00 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:52

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 16:09:00 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:52

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'twice daily (BID)' | Adreanna Pou (b) (4) | 26 Aug 2020 16:09:00 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:52

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 16:09:00 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:52

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Adreanna Pou (b) (4) | 26 Aug 2020 16:09:00 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:52

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 16:09:00 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:52

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '12 Mar 2020' | Adreanna Pou (b) (4) | 26 Aug 2020 16:09:00 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:52

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 26 Aug 2020 16:09:00 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 26 Aug 2020 16:09:00 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 16:09:00 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:52

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 26 Aug 2020 16:09:00 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:52

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 26 Aug 2020 16:09:00 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 16:09:00 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 26 Aug 2020 16:09:00 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:52

[Name of Medication](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) (b) (4) | 27 Aug 2020 17:35:44 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 27 Aug 2020 17:35:44 |
| Data point term sent to Coder | System | 26 Aug 2020 16:12:31 |
| User entered 'levothyroxine' | Adreanna Pou (b) (4) (b) (4) | 26 Aug 2020 16:11:40 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:52

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 26 Aug 2020 16:11:40 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:52

[Indication](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'hypothyroid' | Adreanna Pou (b) (4) | 26 Aug 2020 16:11:40 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:52

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '50' | Adreanna Pou (b) (4) | 26 Aug 2020 16:11:40 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:52

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User closed query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate. ' (Site from DM). | (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) | 23 Nov 2020 15:42:36 |
| Query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate. ' answered with 'updated per query resolution' (Site from DM). | Adreanna Pou (b) (4) (b) (4) | 12 Nov 2020 15:28:47 |
| User entered 'Other (OTHER)' reason for change: Data Entry Error | Adreanna Pou (b) (4) (b) (4) | 12 Nov 2020 15:28:41 |
| User opened query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate. ' (Site from DM). | (b) (4), (b) (6) (b) (4), (b) (6) | 15 Sep 2020 05:02:59 |
| User entered 'mg (mg)' | Adreanna Pou (b) (4) (b) (4) | 26 Aug 2020 16:11:40 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:52

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|--------------------------------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'mcg' reason for change: Data Entry Error | Adreanna Pou (b) (4) | 12 Nov 2020 15:28:41 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 16:11:40 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:52

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Adreanna Pou (b) (4) | 26 Aug 2020 16:11:40 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:52

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 16:11:40 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:52

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Adreanna Pou (b) (4) | 26 Aug 2020 16:11:40 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:52

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 16:11:40 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:52

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'un UNK 2019' | Adreanna Pou (b) (4) | 26 Aug 2020 16:11:40 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:52

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 26 Aug 2020 16:11:40 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 26 Aug 2020 16:11:40 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 16:11:40 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:52

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 26 Aug 2020 16:11:40 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:52

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 16:11:40 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 16:11:40 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 26 Aug 2020 16:11:40 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:52

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: CYANOCOBALAMIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 31 Aug 2020 17:58:34 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 31 Aug 2020 17:58:34 |
| | (b) (4) | |
| Data point term sent to Coder | System | 26 Aug 2020 16:17:51 |
| User entered 'CYANOCOBATAMIN' | Adreanna Pou (b) (4) | 26 Aug 2020 16:17:33 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:52

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 26 Aug 2020 16:17:33 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:52

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' (Site from DM). | (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) | 23 Nov 2020 15:43:55 |
| Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' answered with 'updated per query resolution' (Site from DM). | Adreanna Pou (b) (4) (b) (4) | 12 Nov 2020 15:25:37 |
| User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' (Site from DM). | (b) (4), (b) (6) (b) (4), (b) (6) | 15 Sep 2020 05:04:54 |
| User entered 'B12 deficiency' | Adreanna Pou (b) (4) (b) (4) | 26 Aug 2020 16:17:33 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:52

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '1000' | Adreanna Pou (b) (4) | 26 Aug 2020 16:17:33 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:52

[Dose unit](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User closed query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate.' (Site from DM). | (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) | 23 Nov 2020 15:43:57 |
| Query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate.' answered with 'updated per query resolution' (Site from DM). | Adreanna Pou (b) (4) (b) (4) | 12 Nov 2020 15:26:20 |
| User entered 'Other (OTHER)' reason for change: Data Entry Error | Adreanna Pou (b) (4) (b) (4) | 12 Nov 2020 15:26:07 |
| User opened query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate.' (Site from DM). | (b) (4), (b) (6) (b) (4), (b) (6) | 15 Sep 2020 05:04:06 |
| User entered 'mg (mg)' | Adreanna Pou (b) (4) (b) (4) | 26 Aug 2020 16:17:33 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:52

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|--------------------------------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'mcg' reason for change: Data Entry Error | Adreanna Pou (b) (4) | 12 Nov 2020 15:26:07 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 16:17:33 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:52

[Frequency](#)

| Audit | User | Time (GMT) |
|---------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'every month (QM)' | Adreanna Pou (b) (4) | 26 Aug 2020 16:17:33 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:52

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 16:17:33 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:52

[Route of administration](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Subcutaneous (SUBCUTANEOUS)' | Adreanna Pou (b) (4) | 26 Aug 2020 16:17:33 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:52

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 16:17:33 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:52

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'un UNK 2018' | Adreanna Pou (b) (4) | 26 Aug 2020 16:17:33 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:52

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 26 Aug 2020 16:17:33 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 26 Aug 2020 16:17:33 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 16:17:33 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:52

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 26 Aug 2020 16:17:33 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:52

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 16:17:33 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 16:17:33 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '802 (802)' | System | 26 Aug 2020 16:17:33 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:52

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: FERROUS SULFATE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 27 Aug 2020 17:45:16 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 27 Aug 2020 17:45:16 |
| | (b) (4) | |
| Data point term sent to Coder | System | 26 Aug 2020 16:27:13 |
| User entered 'ferrous sulfate' | Adreanna Pou (b) (4) | 26 Aug 2020 16:27:05 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:52

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 26 Aug 2020 16:27:05 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:52

[Indication](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM). | (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) | 23 Nov 2020 15:44:44 |
| Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' answered with 'updated' (Site from DM). | Adreanna Pou (b) (4) (b) (4) | 12 Nov 2020 15:55:05 |
| User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM). | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Sep 2020 12:38:03 |
| User entered 'anemia' | Adreanna Pou (b) (4) (b) (4) | 26 Aug 2020 16:27:05 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:52

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '325' | Adreanna Pou (b) (4) | 26 Aug 2020 16:27:05 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:52

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'mg (mg)' | Adreanna Pou (b) (4) | 26 Aug 2020 16:27:05 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:52

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 16:27:05 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:52

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Adreanna Pou (b) (4) | 26 Aug 2020 16:27:05 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:52

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 16:27:05 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:52

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Adreanna Pou (b) (4) | 26 Aug 2020 16:27:05 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:52

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 16:27:05 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:52

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'un UNK 1994' | Adreanna Pou (b) (4) | 26 Aug 2020 16:27:05 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:52

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 26 Aug 2020 16:27:05 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 26 Aug 2020 16:27:05 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 26 Aug 2020 16:27:05 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:52

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 26 Aug 2020 16:27:05 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:52

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 16:27:05 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 16:27:05 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 26 Aug 2020 16:27:05 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:52

[Name of Medication](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:01 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| 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: CEFDINIR - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) (b) (4) | 06 Oct 2020 14:14:41 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 06 Oct 2020 14:14:41 |
| Data point term sent to Coder | System | 05 Oct 2020 22:04:54 |
| User entered 'cefdinir' | Jerrica Sullivan (b) (4) (b) (4) | 05 Oct 2020 22:04:17 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:52

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:01 |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'No (N)' | Jerrica Sullivan | 05 Oct 2020 22:04:17 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:52

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:01 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'pansinusitis' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:04:17 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:52

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:01 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '300' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:04:17 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:52

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:01 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'mg (mg)' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:04:17 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:52

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:01 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:04:17 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:52

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:01 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'twice daily (BID)' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:04:17 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:52

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:01 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:04:17 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:52

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:01 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:04:17 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:52

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:01 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:04:17 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:52

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:01 |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '30 Sep 2020' | Jerrica Sullivan | 05 Oct 2020 22:04:17 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:52

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:01 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:04:17 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:01 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' reason for change: Data Entry Error | Adreanna Pou (b) (4) | 12 Nov 2020 15:55:45 |
| | (b) (4) | |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Adreanna Pou (b) (4) | 12 Nov 2020 15:55:32 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:04:17 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------|-------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:01 |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '10 Oct 2020' reason for change: Data Entry Error | Adreanna Pou | 12 Nov 2020 15:55:45 |
| User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System). | System | 12 Nov 2020 15:55:32 |
| User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System). | System | 12 Nov 2020 15:55:26 |
| User closed query 'Future date has been entered. Please correct.' (Site from System). | System | 12 Nov 2020 15:55:26 |
| User entered empty; reason for change Data Entry Error | Adreanna Pou | 12 Nov 2020 15:55:26 |
| User opened query 'Future date has been entered. Please correct.' (Site from System). | System | 05 Oct 2020 22:04:17 |
| User entered '10 Oct 2020' | Jerrica Sullivan | 05 Oct 2020 22:04:17 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:52

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:01 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 05 Oct 2020 22:04:17 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:52

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:01 |
| User entered '2' | (b) (4), (b) (6) System | 05 Oct 2020 22:04:17 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:01 |
| User entered '1' | (b) (4), (b) (6) System | 05 Oct 2020 22:04:17 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:01 |
| User entered '804 (804)' | (b) (4), (b) (6) System | 05 Oct 2020 22:04:17 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:52

[Name of Medication](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 12 Jan 2021 18:17:56 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 12 Jan 2021 18:17:56 |
| | (b) (4) | |
| Data point term sent to Coder | System | 12 Jan 2021 18:16:42 |
| User entered 'ZINC' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:16:24 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:52

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:16:24 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:52

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'COVID-19' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:16:24 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:52

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '100' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:16:24 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:52

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'mg (mg)' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:16:24 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:52

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:16:24 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:52

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:16:24 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:52

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:16:24 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:52

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:16:24 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:52

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:16:24 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:52

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '08 Jan 2021' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:16:24 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:52

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:16:24 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:16:24 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:16:24 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:52

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:16:24 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:52

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Jan 2021 18:16:24 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Jan 2021 18:16:24 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 12 Jan 2021 18:16:24 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:52

Name of Medication

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:08 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| 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) | 12 Jan 2021 18:18:57 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 12 Jan 2021 18:18:57 |
| | (b) (4) | |
| Data point term sent to Coder | System | 12 Jan 2021 18:17:43 |
| User entered 'AZITHROMYCIN' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:16:55 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:52

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:08 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:16:55 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:52

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:08 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'COVID-19' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:16:55 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:52

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:08 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '500' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:16:55 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:52

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:08 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'mg (mg)' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:16:55 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:52

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:08 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:16:55 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:52

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:08 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:16:55 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:52

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:08 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:16:55 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:52

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:08 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:16:55 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:52

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:08 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:16:55 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:52

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:08 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '08 Jan 2021' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:16:55 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:52

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:08 |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '0' | Jerrica Sullivan | 12 Jan 2021 18:16:55 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:08 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:16:55 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:08 |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '08 Jan 2021' | Jerrica Sullivan | 12 Jan 2021 18:16:55 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:52

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:08 |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'No (N)' | Jerrica Sullivan | 12 Jan 2021 18:16:55 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:52

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:08 |
| User entered '1' | (b) (4), (b) (6) System | 12 Jan 2021 18:16:55 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:08 |
| User entered '1' | (b) (4), (b) (6) System | 12 Jan 2021 18:16:55 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:08 |
| User entered '804 (804)' | (b) (4), (b) (6) System | 12 Jan 2021 18:16:55 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:52

Name of Medication

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:13 |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| 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 | 12 Jan 2021 18:18:58 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import | 12 Jan 2021 18:18:58 |
| Data point term sent to Coder | System | 12 Jan 2021 18:17:45 |
| User entered 'AZITHROMYCIN' | Jerrica Sullivan | 12 Jan 2021 18:17:19 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:52

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:13 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:17:19 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:52

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:13 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'COVID-19' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:17:19 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:52

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:13 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '250' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:17:19 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:52

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'mg (mg)' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:17:19 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:52

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:17:19 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:52

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:17:19 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:52

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:13 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:17:19 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:52

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:13 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:17:19 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:52

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:17:19 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:52

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:13 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '09 Jan 2021' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:17:19 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:52

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:13 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:17:19 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:13 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:17:19 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:13 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '12 Jan 2021' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:17:19 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:52

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:13 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:17:19 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:52

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:13 |
| User entered '1' | (b) (4), (b) (6) System | 12 Jan 2021 18:17:19 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:13 |
| User entered '1' | (b) (4), (b) (6) System | 12 Jan 2021 18:17:19 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:13 |
| User entered '804 (804)' | (b) (4), (b) (6) System | 12 Jan 2021 18:17:19 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:52

[Name of Medication](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 12 Jan 2021 18:18:57 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 12 Jan 2021 18:18:57 |
| Data point term sent to Coder | System | 12 Jan 2021 18:17:46 |
| User entered 'VITAMIN D3' | Jerrica Sullivan (b) (4) (b) (4) | 12 Jan 2021 18:17:40 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:52

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:17:40 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:52

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'COVID-19' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:17:40 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:52

[Dose per administration](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| 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). | (b) (4), (b) (6) | 09 Feb 2021 16:03:25 |
| 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 'confirm correct as entered' (Site from DM). | (b) (4), (b) (6) | |
| 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). | Jerrica Sullivan (b) (4) | 08 Feb 2021 16:22:10 |
| User entered '200' | (b) (4) | |
| | (b) (4), (b) (6) | 05 Feb 2021 06:25:06 |
| | (b) (4), (b) (6) | |
| | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:17:40 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:52

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'mg (mg)' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:17:40 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:52

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:17:40 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:52

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:17:40 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:52

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:17:40 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:52

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:17:40 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:52

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:17:40 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:52

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '08 Jan 2021' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:17:40 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:52

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:17:40 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:17:40 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:17:40 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:52

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:17:40 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:52

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Jan 2021 18:17:40 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Jan 2021 18:17:40 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 12 Jan 2021 18:17:40 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:52

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 12 Jan 2021 18:19:57 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 12 Jan 2021 18:19:57 |
| | (b) (4) | |
| Data point term sent to Coder | System | 12 Jan 2021 18:18:46 |
| User entered 'VITAMIN C' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:02 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:52

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:02 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:52

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'COVID-19' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:02 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:52

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '1000' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:02 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:52

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'mg (mg)' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:02 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:52

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:02 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:52

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:02 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:52

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:02 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:52

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:02 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:52

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:02 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:52

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '08 Jan 2021' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:02 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:52

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:02 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:02 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:02 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:52

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:02 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:52

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Jan 2021 18:18:02 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Jan 2021 18:18:02 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 12 Jan 2021 18:18:02 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:52

[Name of Medication](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 12 Jan 2021 21:59:07 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 12 Jan 2021 21:59:07 |
| | (b) (4) | |
| Data point term sent to Coder | System | 12 Jan 2021 18:18:46 |
| User entered 'MELATONIN' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:25 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:52

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:25 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:52

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'COVID-19' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:25 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:52

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '5' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:25 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:52

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'mg (mg)' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:25 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:52

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:25 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:52

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:25 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:52

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:25 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:52

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:25 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:52

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:25 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:52

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '08 Jan 2021' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:25 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:52

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:25 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:25 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:25 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:52

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:25 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:52

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Jan 2021 18:18:25 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Jan 2021 18:18:25 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 12 Jan 2021 18:18:25 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:52

[Name of Medication](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: ENZYMES, PRODUCT: NATTOKINASE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 12 Jan 2021 22:17:42 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 12 Jan 2021 22:17:42 |
| | (b) (4) | |
| Data point term sent to Coder | System | 12 Jan 2021 18:18:46 |
| User entered 'NATTOKINASE' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:43 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:52

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:43 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:52

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'COVID-19' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:43 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:52

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '200' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:43 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:52

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'mg (mg)' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:43 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:52

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:43 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:52

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:43 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:52

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:43 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:52

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:43 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:52

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:43 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:52

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '08 Jan 2021' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:43 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:52

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:43 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:43 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:43 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:52

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 12 Jan 2021 18:18:43 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:52

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Jan 2021 18:18:43 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Jan 2021 18:18:43 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 12 Jan 2021 18:18:43 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:52

Name of Medication

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 09 Apr 2021 16:21:59 |
| | (b) (4) | |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: CAFFEINE;PARACETAMOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 07 Apr 2021 13:41:37 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 07 Apr 2021 13:41:37 |
| | (b) (4) | |
| Data point term sent to Coder | System | 06 Apr 2021 17:23:15 |
| User closed query 'For coding purposes, references indicate different formulations for EXCEDRIN EXTRA STRENGTH. Please provide generic ingredients, complete, accurate trade name and update the term with your response' (Site from System). | System | 06 Apr 2021 17:23:07 |
| Query 'For coding purposes, references indicate different formulations for EXCEDRIN EXTRA STRENGTH. Please provide generic ingredients, complete, accurate trade name and update the term with your response' answered with 'updated' (Site from System). | Jerrica Sullivan (b) (4) | 06 Apr 2021 17:23:07 |
| | (b) (4) | |
| Coding entries removed. | Jerrica Sullivan (b) (4) | 06 Apr 2021 17:22:42 |
| | (b) (4) | |
| Signature has been broken. | Jerrica Sullivan (b) (4) | 06 Apr 2021 17:22:42 |
| | (b) (4) | |
| User entered 'EXTRA STRENGTH EXCEDRIN (acetaminophen/caffiene)' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) | 06 Apr 2021 17:22:42 |
| | (b) (4) | |
| User opened query 'For coding purposes, references indicate different formulations for EXCEDRIN EXTRA STRENGTH. Please provide generic ingredients, complete, accurate trade name and update the term with your response' (Site from System). | Coder Import (b) (4) | 03 Apr 2021 19:49:33 |
| | (b) (4) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:52

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN EXTRA STRENGTH - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 20 Jan 2021 22:16:19 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 20 Jan 2021 22:16:19 |
| Data point term sent to Coder | System | 20 Jan 2021 22:15:09 |
| User entered 'extra strength excedrins' | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:14:20 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:52

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:14:20 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:52

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'headache' | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:14:20 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:52

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 09 Apr 2021 16:21:59 |
| | (b) (4) | |
| Signature has been broken. | Jerrica Sullivan (b) (4) | 06 Apr 2021 17:22:42 |
| | (b) (4) | |
| User entered '500/130' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) | 06 Apr 2021 17:22:42 |
| | (b) (4) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM). | (b) (4), (b) (6) | 23 Feb 2021 13:38:08 |
| | (b) (4), (b) (6) | |
| Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'per site monitor, tablet selection permitted for dosage ' (Site from DM). | Jerrica Sullivan (b) (4) | 22 Feb 2021 13:40:43 |
| | (b) (4) | |
| User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM). | (b) (4), (b) (6) | 21 Feb 2021 08:47:41 |
| | (b) (4), (b) (6) | |
| User entered '2' | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:14:20 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:52

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 09 Apr 2021 16:21:59 |
| | (b) (4) | |
| Signature has been broken. | Jerrica Sullivan (b) (4) | 06 Apr 2021 17:22:42 |
| | (b) (4) | |
| User entered 'mg (mg)' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) | 06 Apr 2021 17:22:42 |
| | (b) (4) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'tablet (TABLET)' | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:14:20 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:52

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:14:20 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:52

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:14:20 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:52

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:14:20 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:52

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:14:20 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:52

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:14:20 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:52

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '13 Jan 2021' | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:14:20 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:52

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:14:20 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:14:20 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:14:20 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:52

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:14:20 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:52

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Jan 2021 22:14:20 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Jan 2021 22:14:20 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 20 Jan 2021 22:14:20 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:52

[Name of Medication](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:44 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN OPIOID DEPENDENCE, PRODUCT: NALOXONE HYDROCHLORIDE, PRODUCTSYNONYM: NARCAN - version WHODrug-Global-B3\\202003. | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 02 Feb 2021 14:22:28 |
| Data point term sent to Coder | (b) (4) | |
| User entered 'narcan' | System | 29 Jan 2021 15:07:11 |
| | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:06:50 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:52

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:44 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:06:50 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:52

Indication

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:44 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| 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) (4), (b) (6) | 23 Feb 2021 13:39:03 |
| | (b) (4), (b) (6) | |
| 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 'log line 4 of ae log is syncope ' (Site from DM). | Jerrica Sullivan (b) (4) | 22 Feb 2021 13:42:14 |
| | (b) (4) | |
| 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) | 21 Feb 2021 08:47:50 |
| | (b) (4), (b) (6) | |
| User entered 'syncope' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:06:50 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:52

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:44 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '.4' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:06:50 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:52

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:44 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'mg (mg)' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:06:50 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:52

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:44 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:06:50 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:52

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:44 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'as needed (PRN)' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:06:50 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:52

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:44 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:06:50 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:52

[Route of administration](#)

| Audit | User | Time (GMT) |
|------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:44 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Intravenous (INTRAVENOUS)' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:06:50 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:52

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:44 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:06:50 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:52

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:44 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '16 Jan 2021' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:06:50 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:52

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:44 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:06:50 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:44 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:06:50 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:44 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '16 Jan 2021' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:06:50 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:52

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:44 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:06:50 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:52

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:44 |
| User entered empty. | (b) (4), (b) (6) System | 29 Jan 2021 15:06:50 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:44 |
| User entered empty. | (b) (4), (b) (6) System | 29 Jan 2021 15:06:50 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:44 |
| User entered empty. | (b) (4), (b) (6) System | 29 Jan 2021 15:06:50 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:52

[Name of Medication](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE HYCLATE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 29 Jan 2021 23:36:33 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 29 Jan 2021 23:36:33 |
| | (b) (4) | |
| Data point term sent to Coder | System | 29 Jan 2021 15:08:11 |
| User entered 'doxycycline hyclate' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:07:39 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:52

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User closed query 'Per DM CLR: Please review Con Med if also used for AE# 3 COVID-19 as the Prophylaxis field is ticked as Yes. If associated, kindly ensure to update CM Indication to reflect the medical condition/diagnosis this con med is being used. Otherwise, please clarify.' (Site from DM). | (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) | 23 Feb 2021 13:40:16 |
| Query 'Per DM CLR: Please review Con Med if also used for AE# 3 COVID-19 as the Prophylaxis field is ticked as Yes. If associated, kindly ensure to update CM Indication to reflect the medical condition/diagnosis this con med is being used. Otherwise, please clarify.' answered with 'this was utilized as prophylaxis after hospitalization to prevent infection from medical procedure' (Site from DM). | Jerrica Sullivan (b) (4) (b) (4) | 22 Feb 2021 13:41:36 |
| User opened query 'Per DM CLR: Please review Con Med if also used for AE# 3 COVID-19 as the Prophylaxis field is ticked as Yes. If associated, kindly ensure to update CM Indication to reflect the medical condition/diagnosis this con med is being used. Otherwise, please clarify.' (Site from DM). | (b) (4), (b) (6) (b) (4), (b) (6) | 21 Feb 2021 08:48:01 |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) (b) (4) | 29 Jan 2021 15:07:39 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:52

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'prophylaxis bacteria infection' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:07:39 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:52

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '100' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:07:39 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:52

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'mg (mg)' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:07:39 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:52

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:07:39 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:52

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'twice daily (BID)' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:07:39 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:52

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:07:39 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:52

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:07:39 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:52

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:07:39 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:52

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '19 Jan 2021' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:07:39 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:52

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:07:39 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:07:39 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:07:39 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:52

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:07:39 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:52

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 29 Jan 2021 15:07:39 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 29 Jan 2021 15:07:39 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 29 Jan 2021 15:07:39 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:52

Name of Medication

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:50 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 29 Jan 2021 15:11:19 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 29 Jan 2021 15:11:19 |
| | (b) (4) | |
| Data point term sent to Coder | System | 29 Jan 2021 15:10:18 |
| User entered 'ibuprofen' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:09:34 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:52

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:50 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:09:34 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:52

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:50 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'headache' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:09:34 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:52

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:50 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '400' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:09:34 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:52

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:50 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'mg (mg)' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:09:34 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:52

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:50 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:09:34 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:52

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:50 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:09:34 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:52

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:50 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:09:34 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:52

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:50 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:09:34 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:52

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:50 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:09:34 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:52

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:50 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '27 Jan 2021' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:09:34 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:52

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:50 |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '0' | Jerrica Sullivan | 29 Jan 2021 15:09:34 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:50 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:09:34 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:50 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '27 Jan 2021' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:09:34 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:52

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:50 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:09:34 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:52

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:50 |
| User entered '1' | (b) (4), (b) (6) System | 29 Jan 2021 15:09:34 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:50 |
| User entered '1' | (b) (4), (b) (6) System | 29 Jan 2021 15:09:34 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:50 |
| User entered '804 (804)' | (b) (4), (b) (6) System | 29 Jan 2021 15:09:34 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:52

Name of Medication

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:56 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003. | (b) (4), (b) (6) Coder Import (b) (4) (b) (4) | 18 Apr 2021 16:21:59 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 18 Apr 2021 16:21:59 |
| User signature succeeded. | Rambod Rouhbakhsh (b) (4) | 02 Apr 2021 13:41:48 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 15 Mar 2021 15:17:58 |
| 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 Mar 2021 15:17:58 |
| Data point term sent to Coder | System | 29 Jan 2021 15:12:19 |
| User entered 'sodium chloride' | Jerrica Sullivan (b) (4) (b) (4) | 29 Jan 2021 15:11:41 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:52

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:56 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:11:41 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:52

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:56 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'syncope' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:11:41 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:52

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:56 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '10' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:11:41 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:52

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:56 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'mL (mL)' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:11:41 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:52

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:56 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:11:41 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:52

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:56 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:11:41 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:52

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:56 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:11:41 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:52

[Route of administration](#)

| Audit | User | Time (GMT) |
|------------------------------------------|-------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:56 |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'Intravenous (INTRAVENOUS)' | Jerrica Sullivan | 29 Jan 2021 15:11:41 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:52

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:56 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:11:41 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:52

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:56 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '16 Jan 2021' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:11:41 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:52

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:56 |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '0' | Jerrica Sullivan | 29 Jan 2021 15:11:41 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:56 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:11:41 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:56 |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '16 Jan 2021' | Jerrica Sullivan | 29 Jan 2021 15:11:41 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:52

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:56 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:11:41 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:52

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:56 |
| User entered '1' | (b) (4), (b) (6) System | 29 Jan 2021 15:11:41 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:56 |
| User entered '1' | (b) (4), (b) (6) System | 29 Jan 2021 15:11:41 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:16:56 |
| User entered '804 (804)' | (b) (4), (b) (6) System | 29 Jan 2021 15:11:41 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:52

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) (b) (4) | 29 Jan 2021 15:13:19 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 29 Jan 2021 15:13:19 |
| Data point term sent to Coder | System | 29 Jan 2021 15:12:20 |
| User entered 'lisinopril' | Jerrica Sullivan (b) (4) (b) (4) | 29 Jan 2021 15:12:08 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:52

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:12:08 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:52

[Indication](#)

| Audit | User | Time (GMT) |
|------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'hypertension ' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:12:08 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:52

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '10' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:12:08 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:52

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'mg (mg)' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:12:08 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:52

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:12:08 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:52

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:12:08 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:52

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:12:08 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:52

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:12:08 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:52

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:12:08 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:52

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '16 Jan 2021' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:12:08 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:52

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:12:08 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) | 05 Feb 2021 18:52:20 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:12:08 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '02 Feb 2021' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) | 05 Feb 2021 18:52:20 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:12:08 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:52

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:12:08 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:52

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 29 Jan 2021 15:12:08 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 29 Jan 2021 15:12:08 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 29 Jan 2021 15:12:08 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:52

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) (b) (4) | 29 Jan 2021 15:14:19 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 29 Jan 2021 15:14:19 |
| Data point term sent to Coder | System | 29 Jan 2021 15:13:20 |
| User entered 'amlodipine' | Jerrica Sullivan (b) (4) (b) (4) | 29 Jan 2021 15:12:36 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:52

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:12:36 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:52

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'hypertension' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:12:36 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:52

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '10' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:12:36 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:52

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'mg (mg)' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:12:36 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:52

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:12:36 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:52

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:12:36 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:52

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:12:36 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:52

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:12:36 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:52

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:12:36 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:52

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '16 Jan 2021' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:12:36 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:52

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:12:36 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:12:36 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:12:36 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:52

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 29 Jan 2021 15:12:36 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:52

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 29 Jan 2021 15:12:36 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 29 Jan 2021 15:12:36 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 29 Jan 2021 15:12:36 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:52

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 05 Feb 2021 18:54:47 |
| | (b) (4) | |
| User coded data point as Term Coded data point by | Coder Import (b) (4) | 05 Feb 2021 18:54:47 |
| User: Coder System - version WHODrug-Global-B3\\202003. | (b) (4) | |
| Data point term sent to Coder | System | 05 Feb 2021 18:53:40 |
| User entered 'lisinopril' | Jerrica Sullivan (b) (4) | 05 Feb 2021 18:52:49 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:52

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 05 Feb 2021 18:52:49 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:52

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'hypertension' | Jerrica Sullivan (b) (4) | 05 Feb 2021 18:52:49 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:52

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '5' | Jerrica Sullivan (b) (4) | 05 Feb 2021 18:52:49 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:52

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'mg (mg)' | Jerrica Sullivan (b) (4) | 05 Feb 2021 18:52:49 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:52

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 05 Feb 2021 18:52:49 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:52

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Jerrica Sullivan (b) (4) | 05 Feb 2021 18:52:49 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:52

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 05 Feb 2021 18:52:49 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:52

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Jerrica Sullivan (b) (4) | 05 Feb 2021 18:52:49 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:52

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 05 Feb 2021 18:52:49 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:52

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '03 Feb 2021' | Jerrica Sullivan (b) (4) | 05 Feb 2021 18:52:49 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:52

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 05 Feb 2021 18:52:49 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 05 Feb 2021 18:52:49 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 05 Feb 2021 18:52:49 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:52

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 05 Feb 2021 18:52:49 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:52

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Feb 2021 18:52:49 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Feb 2021 18:52:49 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 05 Feb 2021 18:52:49 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:52

[Name of Medication](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:19 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 05 Feb 2021 18:55:58 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 05 Feb 2021 18:55:58 |
| | (b) (4) | |
| Data point term sent to Coder | System | 05 Feb 2021 18:54:41 |
| User entered 'ondansetron' | Jerrica Sullivan (b) (4) | 05 Feb 2021 18:54:19 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:52

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:19 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 05 Feb 2021 18:54:19 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:52

Indication

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:19 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User closed query 'Per DM CLR: Please note there is no ongoing MH condition that matches this Con Med indication. Please review the Con Med use and add a medical condition in the MH eCRF and also ensure to update CM eCRF's: Prophylaxis field to NO. Please update as appropriate.' (Site from DM). | (b) (4) | |
| | (b) (4), (b) (6) | 23 Feb 2021 13:41:18 |
| | (b) (4), (b) (6) | |
| Query 'Per DM CLR: Please note there is no ongoing MH condition that matches this Con Med indication. Please review the Con Med use and add a medical condition in the MH eCRF and also ensure to update CM eCRF's: Prophylaxis field to NO. Please update as appropriate.' answered with 'this was utilized in hospital for prophylaxis of nausea while receiving IV medication ' (Site from DM). | Jerrica Sullivan (b) (4) | 22 Feb 2021 13:42:54 |
| | (b) (4) | |
| User opened query 'Per DM CLR: Please note there is no ongoing MH condition that matches this Con Med indication. Please review the Con Med use and add a medical condition in the MH eCRF and also ensure to update CM eCRF's: Prophylaxis field to NO. Please update as appropriate.' (Site from DM). | (b) (4), (b) (6) | 21 Feb 2021 08:48:20 |
| | (b) (4), (b) (6) | |
| User entered 'nausea prophylaxis' | Jerrica Sullivan (b) (4) | 05 Feb 2021 18:54:19 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:52

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:19 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '2' | Jerrica Sullivan (b) (4) | 05 Feb 2021 18:54:19 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:52

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:19 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'mL (mL)' | Jerrica Sullivan (b) (4) | 05 Feb 2021 18:54:19 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:52

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:19 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 05 Feb 2021 18:54:19 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:52

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:19 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Jerrica Sullivan (b) (4) | 05 Feb 2021 18:54:19 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:52

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:19 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 05 Feb 2021 18:54:19 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:52

[Route of administration](#)

| Audit | User | Time (GMT) |
|------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:19 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Intravenous (INTRAVENOUS)' | Jerrica Sullivan (b) (4) | 05 Feb 2021 18:54:19 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:52

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:19 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 05 Feb 2021 18:54:19 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:52

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:19 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '16 Jan 2021' | Jerrica Sullivan (b) (4) | 05 Feb 2021 18:54:19 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:52

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:19 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 05 Feb 2021 18:54:19 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:19 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 05 Feb 2021 18:54:19 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:19 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '16 Jan 2021' | Jerrica Sullivan (b) (4) | 05 Feb 2021 18:54:19 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:52

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:19 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 05 Feb 2021 18:54:19 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:52

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:19 |
| User entered '1' | (b) (4), (b) (6) System | 05 Feb 2021 18:54:19 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:19 |
| User entered '1' | (b) (4), (b) (6) System | 05 Feb 2021 18:54:19 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:19 |
| User entered '804 (804)' | (b) (4), (b) (6) System | 05 Feb 2021 18:54:19 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:52

Name of Medication

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|----------------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:25 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 15 Mar 2021 21:23:33 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 15 Mar 2021 21:23:33 |
| Data point term sent to Coder Coding entries removed. | System Jerrica Sullivan (b) (4) | 15 Mar 2021 21:23:08 15 Mar 2021 21:22:52 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 11 Mar 2021 21:41:56 |
| 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 Mar 2021 21:41:56 |
| Data point term sent to Coder Coding entries removed. | System Jerrica Sullivan (b) (4) | 11 Mar 2021 21:41:36 11 Mar 2021 21:40:55 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 25 Feb 2021 21:16:00 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 25 Feb 2021 21:16:00 |
| Data point term sent to Coder User entered 'acetaminophen' | System Jerrica Sullivan (b) (4) | 25 Feb 2021 21:15:36 25 Feb 2021 21:15:06 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:52

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:25 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:15:06 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:52

[Indication](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:25 |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'pre/post operative PAIN (SURGICAL SITE-PACEMAKER)' reason for change: Data Entry Error | Jerrica Sullivan | 15 Mar 2021 21:22:52 |
| User closed query 'Per CDM: Please note, there is no AE that matches this Con Med indication during this timeframe? Please review and add an entry and applicable details to the relevant eCRF as appropriate or, provide record number this indication pertains to. Thank you' (Site from DM). | Jerrica Sullivan | 15 Mar 2021 12:29:26 |
| Query 'Per CDM: Please note, there is no AE that matches this Con Med indication during this timeframe? Please review and add an entry and applicable details to the relevant eCRF as appropriate or, provide record number this indication pertains to. Thank you' answered with 'listed under con procedures ' (Site from DM). | Jerrica Sullivan | 12 Mar 2021 17:17:45 |
| User opened query 'Per CDM: Please note, there is no AE that matches this Con Med indication during this timeframe? Please review and add an entry and applicable details to the relevant eCRF as appropriate or, provide record number this indication pertains to. Thank you' (Site from DM). | Jerrica Sullivan | 12 Mar 2021 12:46:25 |
| User closed query 'Per DM CLR: Please update the indication to reflect the location or type of PAIN. Review and update indication and ensure to update Adverse event eCRF as appropriate. ' (Site from DM). | Jerrica Sullivan | 12 Mar 2021 12:45:29 |
| User entered 'PAIN (SURGICAL SITE-pacemaker)' reason for change: Data Entry Error | Jerrica Sullivan | 11 Mar 2021 21:41:14 |
| Query 'Per DM CLR: Please update the indication to reflect the location or type of PAIN. Review and update indication and ensure to update Adverse event eCRF as appropriate. ' answered with 'updated' (Site from DM). | Jerrica Sullivan | 11 Mar 2021 21:41:02 |
| User entered 'PAIN (surgical site)' reason for change: Data Entry Error | Jerrica Sullivan | 11 Mar 2021 21:40:55 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:52

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------|
| User opened query 'Per DM CLR: Please update the indication to reflect the location or type of PAIN. Review and update indication and ensure to update Adverse event eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) (b) (4), (b) (6) | 11 Mar 2021 07:56:22 |
| User entered 'pain' | Jerrica Sullivan (b) (4) (b) (4) | 25 Feb 2021 21:15:06 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:52

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:25 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '1300' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:15:06 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:52

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:25 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'mg (mg)' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:15:06 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:52

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:25 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:15:06 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:52

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:25 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:15:06 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:52

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:25 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:15:06 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:52

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:25 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:15:06 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:52

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:25 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:15:06 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:52

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:25 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '16 Jan 2021' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:15:06 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:52

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:25 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:15:06 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:25 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:15:06 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:25 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '19 Jan 2021' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:15:06 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:52

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:25 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:15:06 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:52

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:25 |
| User entered '1' | (b) (4), (b) (6) System | 25 Feb 2021 21:15:06 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:25 |
| User entered '1' | (b) (4), (b) (6) System | 25 Feb 2021 21:15:06 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:25 |
| User entered '804 (804)' | (b) (4), (b) (6) System | 25 Feb 2021 21:15:06 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:52

[Name of Medication](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|----------------------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:28 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\202003. | (b) (4) Coder Import (b) (4) | 19 Mar 2021 07:58:53 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003. | Coder Import (b) (4) (b) (4) | 19 Mar 2021 07:58:53 |
| Data point term sent to Coder Coding entries removed. | System Adreanna Pou (b) (4) | 18 Mar 2021 19:35:17 18 Mar 2021 19:34:26 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\202003. | (b) (4) Coder Import (b) (4) | 12 Mar 2021 11:20:46 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003. | Coder Import (b) (4) (b) (4) | 12 Mar 2021 11:20:46 |
| Data point term sent to Coder User entered 'docusate Colace' | System Jerrica Sullivan (b) (4) (b) (4) | 25 Feb 2021 21:16:36 25 Feb 2021 21:16:01 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:52

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:28 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:16:01 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:52

[Indication](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:28 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'prophylactic CONSTIPATION' reason for change: Data Entry Error | Adreanna Pou (b) (4) | 18 Mar 2021 19:34:26 |
| | (b) (4) | |
| User entered 'constipation' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:16:01 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:52

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:28 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '100' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:16:01 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:52

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:28 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'mg (mg)' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:16:01 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:52

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:28 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:16:01 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:52

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:28 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:16:01 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:52

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:28 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:16:01 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:52

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:28 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:16:01 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:52

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:28 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:16:01 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:52

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:28 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '16 Jan 2021' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:16:01 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:52

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:28 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:16:01 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:28 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:16:01 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:28 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '19 Jan 2021' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:16:01 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:52

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:28 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:16:01 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:52

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:28 |
| User entered '1' | (b) (4), (b) (6) System | 25 Feb 2021 21:16:01 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:28 |
| User entered '1' | (b) (4), (b) (6) System | 25 Feb 2021 21:16:01 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:28 |
| User entered '804 (804)' | (b) (4), (b) (6) System | 25 Feb 2021 21:16:01 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:05:52

Name of Medication

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:33 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: PROMETHAZINE - version WHODrug-Global-B3\\202003. | (b) (4) | |
| | Coder Import (b) (4) | 12 Mar 2021 08:09:41 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 12 Mar 2021 08:09:41 |
| | (b) (4) | |
| Data point term sent to Coder | System | 25 Feb 2021 21:17:37 |
| User entered 'promethazine' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:17:26 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:05:52

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:33 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User closed query 'Per DM CLR: The indication signifies prophylaxis. However, the response in this field reflects otherwise, Please review and update to Yes as appropriate. Else, provide justification. ' (Site from DM). | (b) (4) | |
| | (b) (4), (b) (6) | 12 Mar 2021 12:46:53 |
| | (b) (4), (b) (6) | |
| Query 'Per DM CLR: The indication signifies prophylaxis. However, the response in this field reflects otherwise, Please review and update to Yes as appropriate. Else, provide justification. ' answered with 'updated' (Site from DM). | Jerrica Sullivan (b) (4) | 11 Mar 2021 21:41:40 |
| | (b) (4) | |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) | 11 Mar 2021 21:41:34 |
| | (b) (4) | |
| User opened query 'Per DM CLR: The indication signifies prophylaxis. However, the response in this field reflects otherwise, Please review and update to Yes as appropriate. Else, provide justification. ' (Site from DM). | (b) (4), (b) (6) | 11 Mar 2021 07:56:51 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:17:26 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:05:52

[Indication](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:33 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'prophylactic n//v' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:17:26 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:05:52

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:33 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '12.5' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:17:26 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:05:52

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:33 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'mg (mg)' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:17:26 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:05:52

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:33 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:17:26 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:05:52

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:33 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:17:26 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:05:52

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:33 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:17:26 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:05:52

[Route of administration](#)

| Audit | User | Time (GMT) |
|------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:33 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Intravenous (INTRAVENOUS)' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:17:26 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:05:52

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:33 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:17:26 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:05:52

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:33 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '17 Jan 2021' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:17:26 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:05:52

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:33 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:17:26 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:33 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:17:26 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:33 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '17 Jan 2021' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:17:26 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:05:52

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:33 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:17:26 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:05:52

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:33 |
| User entered '1' | (b) (4), (b) (6) System | 25 Feb 2021 21:17:26 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:33 |
| User entered '1' | (b) (4), (b) (6) System | 25 Feb 2021 21:17:26 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:33 |
| User entered '804 (804)' | (b) (4), (b) (6) System | 25 Feb 2021 21:17:26 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:05:52

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:49 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: STOMATOLOGICAL PREPARATIONS, ATC: STOMATOLOGICAL PREPARATIONS, ATC: ANTIINFECTIVES AND ANTISEPTICS FOR LOCAL ORAL TREATMENT, PRODUCT: CHLORHEXIDINE - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) (b) (4) | 01 Mar 2021 13:11:49 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 01 Mar 2021 13:11:49 |
| Data point term sent to Coder | System | 25 Feb 2021 21:20:39 |
| User entered 'chlorhexidine 2%' | Jerrica Sullivan (b) (4) (b) (4) | 25 Feb 2021 21:20:00 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:05:52

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:49 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:20:00 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:05:52

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:49 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'prophylactic for infection' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:20:00 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:05:52

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:49 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'I' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:20:00 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:05:52

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:49 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Other (OTHER)' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:20:00 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:05:52

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:49 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'application' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:20:00 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:05:52

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:49 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:20:00 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:05:52

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:49 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:20:00 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:05:52

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:49 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Topical (TOPICAL)' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:20:00 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:05:52

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:49 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:20:00 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:05:52

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:49 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '17 Jan 2021' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:20:00 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:05:52

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:49 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '0' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:20:00 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:49 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:20:00 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:49 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '18 Jan 2021' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:20:00 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:05:52

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:49 |
| User signature succeeded. | (b) (4), (b) (6) | |
| | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 25 Feb 2021 21:20:00 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:05:52

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:49 |
| User entered '1' | (b) (4), (b) (6) System | 25 Feb 2021 21:20:00 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:49 |
| User entered '1' | (b) (4), (b) (6) System | 25 Feb 2021 21:20:00 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 09:17:49 |
| User entered '804 (804)' | (b) (4), (b) (6) System | 25 Feb 2021 21:20:00 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:05:52

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 19 Apr 2021 22:04:43 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 19 Apr 2021 22:04:43 |
| | (b) (4) | |
| Data point term sent to Coder | System | 19 Apr 2021 22:03:47 |
| User entered 'DOXYCYCLINE' | Adreanna Pou (b) (4) | 19 Apr 2021 22:02:49 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:05:52

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 19 Apr 2021 22:02:49 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:05:52

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'SINUSITIS' | Adreanna Pou (b) (4) | 19 Apr 2021 22:02:49 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:05:52

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '100' | Adreanna Pou (b) (4) | 19 Apr 2021 22:02:49 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:05:52

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'mg (mg)' | Adreanna Pou (b) (4) | 19 Apr 2021 22:02:49 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:05:52

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 22:02:49 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:05:52

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'twice daily (BID)' | Adreanna Pou (b) (4) | 19 Apr 2021 22:02:49 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:05:52

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 22:02:49 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:05:52

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Adreanna Pou (b) (4) | 19 Apr 2021 22:02:49 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:05:52

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 22:02:49 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:05:52

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '15 Apr 2021' | Adreanna Pou (b) (4) | 19 Apr 2021 22:02:49 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:05:52

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered '0' | Adreanna Pou (b) (4) | 19 Apr 2021 22:02:49 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:05:52

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Adreanna Pou (b) (4) | 19 Apr 2021 22:02:49 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:05:52

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered empty. | Adreanna Pou (b) (4) | 19 Apr 2021 22:02:49 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:05:52

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 23 Apr 2021 15:21:06 |
| | (b) (4) | |
| User entered 'No (N)' | Adreanna Pou (b) (4) | 19 Apr 2021 22:02:49 |
| | (b) (4) | |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:05:52

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 19 Apr 2021 22:02:49 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 19 Apr 2021 22:02:49 |

US3232056

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:05:52

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 19 Apr 2021 22:02:49 |

US3232056

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:05:52

[Were any concomitant procedures performed?](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | May 2021 10:34:45 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:15:49 |
| | (b) (4) | |
| User entered 'No (N)' | Jerrica Sullivan (b) (4) | 18 Aug 2020 12:47:00 |
| | (b) (4) | |

US3232056

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:05:52

Procedure/Surgery date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered '18 Jan 2021' | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:16:08 |
| | (b) (4) | |

US3232056

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:05:52

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'pacemaker placement' | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:16:08 |
| | (b) (4) | |

US3232056

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:05:52

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered 'Adverse Event (AE)' | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:16:08 |
| | (b) (4) | |

US3232056

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:05:52

[If indication is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| User entered empty. | Jerrica Sullivan (b) (4) | 20 Jan 2021 22:16:08 |
| | (b) (4) | |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered | System | 13 Jan 2021 17:47:33 |
| 'USA-US105-2021-MRNA-1273-P301000002' | | |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

Serious

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 17 Feb 2021 21:41:27 |
| | (b) (4), (b) (6) | |
| Un-reviewed for Safety. | System | 12 Feb 2021 20:38:13 |
| User entered 'Yes (Y)' | System | 12 Feb 2021 20:38:13 |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 17 Feb 2021 21:41:27 |
| | (b) (4), (b) (6) | |
| Un-reviewed for Safety. | System | 12 Feb 2021 20:38:13 |
| User entered 'Yes (Y)' | System | 12 Feb 2021 20:38:13 |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'Rambod' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'Rouhbakhsh' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'MediSync Clinical Research Hattiesburg Clinic' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

Site Address: [City](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'Petal' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

Site Address: State

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'MS' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered '39465' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'US' | System | 13 Jan 2021 17:48:20 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '5' | System | 16 Mar 2021 13:29:44 |
| User entered '4' | System | 05 Mar 2021 14:39:14 |
| User entered '3' | System | 23 Feb 2021 19:16:15 |
| User entered '2' | System | 17 Feb 2021 21:41:45 |
| User entered '1' | System | 13 Jan 2021 17:48:20 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered | System | 13 Jan 2021 17:47:33 |
| 'USA-US105-2021-MRNA-1273-P301000002' | | |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

Serious

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 17 Feb 2021 21:41:27 |
| | (b) (4), (b) (6) | |
| Un-reviewed for Safety. | System | 12 Feb 2021 20:38:13 |
| User entered 'Yes (Y)' | System | 12 Feb 2021 20:38:13 |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 17 Feb 2021 21:41:27 |
| | (b) (4), (b) (6) | |
| Un-reviewed for Safety. | System | 12 Feb 2021 20:38:13 |
| User entered 'Yes (Y)' | System | 12 Feb 2021 20:38:13 |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'Rambod' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'Rouhbakhsh' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

Site Address: Street

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'MediSync Clinical Research Hattiesburg Clinic' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'Petal' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'MS' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered '39465' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'US' | System | 13 Jan 2021 17:48:20 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '5' | System | 16 Mar 2021 13:29:44 |
| User entered '4' | System | 05 Mar 2021 14:39:14 |
| User entered '3' | System | 23 Feb 2021 19:16:15 |
| User entered '2' | System | 17 Feb 2021 21:41:45 |
| User entered '1' | System | 13 Jan 2021 17:48:20 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:05:52

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|---------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '13/Jan/2021 12:48' | (b) (4) System | 13 Jan 2021 17:48:20 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:05:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| User entered 'I' | (b) (4), (b) (6) (b) (4), (b) (6) | 13 Jan 2021 17:48:20 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered | System | 13 Jan 2021 17:47:33 |
| 'USA-US105-2021-MRNA-1273-P301000002' | | |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

Serious

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 17 Feb 2021 21:41:27 |
| | (b) (4), (b) (6) | |
| Un-reviewed for Safety. | System | 12 Feb 2021 20:38:13 |
| User entered 'Yes (Y)' | System | 12 Feb 2021 20:38:13 |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

Death

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 17 Feb 2021 21:41:27 |
| | (b) (4), (b) (6) | |
| Un-reviewed for Safety. | System | 12 Feb 2021 20:38:13 |
| User entered 'Yes (Y)' | System | 12 Feb 2021 20:38:13 |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'Rambod' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'Rouhbakhsh' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'MediSync Clinical Research Hattiesburg Clinic' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'Petal' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'MS' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered '39465' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'US' | System | 13 Jan 2021 17:48:20 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '5' | System | 16 Mar 2021 13:29:44 |
| User entered '4' | System | 05 Mar 2021 14:39:14 |
| User entered '3' | System | 23 Feb 2021 19:16:15 |
| User entered '2' | System | 17 Feb 2021 21:41:45 |
| User entered '1' | System | 13 Jan 2021 17:48:20 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:05:52

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|---------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '17/Feb/2021 16:41' | (b) (4) System | 17 Feb 2021 21:41:45 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:05:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 05 Mar 2021 14:38:44 |
| User entered 'I' | (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6) | 17 Feb 2021 21:41:45 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered | System | 13 Jan 2021 17:47:33 |
| 'USA-US105-2021-MRNA-1273-P301000002' | | |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

Serious

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 17 Feb 2021 21:41:27 |
| | (b) (4), (b) (6) | |
| Un-reviewed for Safety. | System | 12 Feb 2021 20:38:13 |
| User entered 'Yes (Y)' | System | 12 Feb 2021 20:38:13 |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 17 Feb 2021 21:41:27 |
| | (b) (4), (b) (6) | |
| Un-reviewed for Safety. | System | 12 Feb 2021 20:38:13 |
| User entered 'Yes (Y)' | System | 12 Feb 2021 20:38:13 |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'Rambod' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'Rouhbakhsh' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'MediSync Clinical Research Hattiesburg Clinic' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'Petal' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

Site Address: State

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'MS' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered '39465' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'US' | System | 13 Jan 2021 17:48:20 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '5' | System | 16 Mar 2021 13:29:44 |
| User entered '4' | System | 05 Mar 2021 14:39:14 |
| User entered '3' | System | 23 Feb 2021 19:16:15 |
| User entered '2' | System | 17 Feb 2021 21:41:45 |
| User entered '1' | System | 13 Jan 2021 17:48:20 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:05:52

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|---------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '23/Feb/2021 14:16' | (b) (4) System | 23 Feb 2021 19:16:15 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:05:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 05 Mar 2021 14:38:44 |
| User entered 'I' | (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6) | 23 Feb 2021 19:16:15 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered | System | 13 Jan 2021 17:47:33 |
| 'USA-US105-2021-MRNA-1273-P301000002' | | |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

Serious

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 17 Feb 2021 21:41:27 |
| | (b) (4), (b) (6) | |
| Un-reviewed for Safety. | System | 12 Feb 2021 20:38:13 |
| User entered 'Yes (Y)' | System | 12 Feb 2021 20:38:13 |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 17 Feb 2021 21:41:27 |
| | (b) (4), (b) (6) | |
| Un-reviewed for Safety. | System | 12 Feb 2021 20:38:13 |
| User entered 'Yes (Y)' | System | 12 Feb 2021 20:38:13 |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'Rambod' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'Rouhbakhsh' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

Site Address: Street

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'MediSync Clinical Research Hattiesburg Clinic' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

Site Address: [City](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'Petal' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'MS' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered '39465' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'US' | System | 13 Jan 2021 17:48:20 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '5' | System | 16 Mar 2021 13:29:44 |
| User entered '4' | System | 05 Mar 2021 14:39:14 |
| User entered '3' | System | 23 Feb 2021 19:16:15 |
| User entered '2' | System | 17 Feb 2021 21:41:45 |
| User entered '1' | System | 13 Jan 2021 17:48:20 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:05:52

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|---------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '05/Mar/2021 09:39' | (b) (4) System | 05 Mar 2021 14:39:14 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:05:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'I' | (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) | 05 Mar 2021 14:39:14 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered | System | 13 Jan 2021 17:47:33 |
| 'USA-US105-2021-MRNA-1273-P301000002' | | |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

Serious

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 17 Feb 2021 21:41:27 |
| | (b) (4), (b) (6) | |
| Un-reviewed for Safety. | System | 12 Feb 2021 20:38:13 |
| User entered 'Yes (Y)' | System | 12 Feb 2021 20:38:13 |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 17 Feb 2021 21:41:27 |
| | (b) (4), (b) (6) | |
| Un-reviewed for Safety. | System | 12 Feb 2021 20:38:13 |
| User entered 'Yes (Y)' | System | 12 Feb 2021 20:38:13 |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'Rambod' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'Rouhbakhsh' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'MediSync Clinical Research Hattiesburg Clinic' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'Petal' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'MS' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered '39465' | System | 13 Jan 2021 17:47:33 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:48:24 |
| | (b) (4), (b) (6) | |
| User entered 'US' | System | 13 Jan 2021 17:48:20 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '5' | System | 16 Mar 2021 13:29:44 |
| User entered '4' | System | 05 Mar 2021 14:39:14 |
| User entered '3' | System | 23 Feb 2021 19:16:15 |
| User entered '2' | System | 17 Feb 2021 21:41:45 |
| User entered '1' | System | 13 Jan 2021 17:48:20 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:05:52

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|---------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '16/Mar/2021 09:29' | (b) (4) System | 16 Mar 2021 13:29:44 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:05:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:13 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'I' | (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) | 16 Mar 2021 13:29:44 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered | System | 21 Jan 2021 14:16:16 |
| 'USA-US105-2021-MRNA-1273-P301000003' | | |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

Serious

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'Yes (Y)' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'Yes (Y)' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'Rambod' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'Rouhbakhsh' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'MediSync Clinical Research Hattiesburg Clinic' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'Petal' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'MS' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered '39465' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 15:08:28 |
| User entered 'US' | (b) (4), (b) (6) System | 21 Jan 2021 14:17:43 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '4' | System | 12 Feb 2021 20:29:08 |
| User entered '3' | System | 12 Feb 2021 18:52:02 |
| User entered '2' | System | 25 Jan 2021 15:08:48 |
| User entered '1' | System | 21 Jan 2021 14:17:43 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered | System | 21 Jan 2021 14:16:16 |
| 'USA-US105-2021-MRNA-1273-P301000003' | | |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

Serious

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'Yes (Y)' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| User entered 'No (N)' | (b) (4), (b) (6) System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'Yes (Y)' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'Rambod' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'Rouhbakhsh' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'MediSync Clinical Research Hattiesburg Clinic' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'Petal' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'MS' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered '39465' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 15:08:28 |
| User entered 'US' | (b) (4), (b) (6) System | 21 Jan 2021 14:17:43 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '4' | System | 12 Feb 2021 20:29:08 |
| User entered '3' | System | 12 Feb 2021 18:52:02 |
| User entered '2' | System | 25 Jan 2021 15:08:48 |
| User entered '1' | System | 21 Jan 2021 14:17:43 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:05:52

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|---------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '21/Jan/2021 14:17' | (b) (4) System | 21 Jan 2021 14:17:43 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:05:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 15:08:28 |
| User entered '1' | (b) (4), (b) (6) (b) (4), (b) (6) | 21 Jan 2021 14:17:43 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered | System | 21 Jan 2021 14:16:16 |
| 'USA-US105-2021-MRNA-1273-P301000003' | | |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

Serious

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'Yes (Y)' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'Yes (Y)' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'Rambod' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'Rouhbakhsh' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'MediSync Clinical Research Hattiesburg Clinic' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'Petal' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

Site Address: State

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'MS' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered '39465' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 15:08:28 |
| User entered 'US' | (b) (4), (b) (6) System | 21 Jan 2021 14:17:43 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '4' | System | 12 Feb 2021 20:29:08 |
| User entered '3' | System | 12 Feb 2021 18:52:02 |
| User entered '2' | System | 25 Jan 2021 15:08:48 |
| User entered '1' | System | 21 Jan 2021 14:17:43 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:05:52

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|---------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '25/Jan/2021 15:08' | (b) (4) System | 25 Jan 2021 15:08:48 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:05:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'I' | (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) | 25 Jan 2021 15:08:48 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered | System | 21 Jan 2021 14:16:16 |
| 'USA-US105-2021-MRNA-1273-P301000003' | | |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

Serious

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| User entered 'No (N)' | (b) (4), (b) (6) System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'Yes (Y)' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| User entered 'No (N)' | (b) (4), (b) (6) System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| User entered 'No (N)' | (b) (4), (b) (6) System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'Rambod' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'Rouhbakhsh' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'MediSync Clinical Research Hattiesburg Clinic' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'Petal' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'MS' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered '39465' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Jan 2021 15:08:28 |
| | (b) (4), (b) (6) | |
| User entered 'US' | System | 21 Jan 2021 14:17:43 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '4' | System | 12 Feb 2021 20:29:08 |
| User entered '3' | System | 12 Feb 2021 18:52:02 |
| User entered '2' | System | 25 Jan 2021 15:08:48 |
| User entered '1' | System | 21 Jan 2021 14:17:43 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:05:52

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|---------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '12/Feb/2021 12:51' | (b) (4) System | 12 Feb 2021 18:52:02 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:05:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'I' | (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) | 12 Feb 2021 18:52:02 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered | System | 21 Jan 2021 14:16:16 |
| 'USA-US105-2021-MRNA-1273-P301000003' | | |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

Serious

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'Yes (Y)' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'Yes (Y)' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| User entered 'No (N)' | (b) (4), (b) (6) System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'Rambod' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'Rouhbakhsh' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'MediSync Clinical Research Hattiesburg Clinic' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'Petal' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered 'MS' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 21 Jan 2021 14:17:32 |
| | (b) (4), (b) (6) | |
| User entered '39465' | System | 21 Jan 2021 14:16:16 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Jan 2021 15:08:28 |
| | (b) (4), (b) (6) | |
| User entered 'US' | System | 21 Jan 2021 14:17:43 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '4' | System | 12 Feb 2021 20:29:08 |
| User entered '3' | System | 12 Feb 2021 18:52:02 |
| User entered '2' | System | 25 Jan 2021 15:08:48 |
| User entered '1' | System | 21 Jan 2021 14:17:43 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:05:52

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|---------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered '12/Feb/2021 14:29' | (b) (4) System | 12 Feb 2021 20:29:08 |

US3232056

Folder: SAE USA-US105-2021-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:05:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:42:27 |
| User signature succeeded. | (b) (4), (b) (6) Rambod Rouhbakhsh | 02 Apr 2021 13:41:48 |
| User entered 'I' | (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) | 12 Feb 2021 20:29:08 |