

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: COHORT_SELECTION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Cohort Selection

DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.

| | | |
|----|---|-----------------|
| 1. | Select appropriate response - Protocol version | 24 JUL 2020 |
| 2. | Select appropriate response - What cohort does the subject belong to? | STAGE 3 COHORTS |

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Informed Consent

| | | |
|----|--------------|--|
| 1. | Consent Was: | OBTAINED Date Written Consent Obtained Aug/31/2020 |
|----|--------------|--|

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: DEMOGRAPHY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Demography

| | | |
|----|---------------------------------|--|
| 1. | Subject ID | [10971064] |
| 2. | Birth Date: | (b) (6) 1942 |
| 3. | Sex: | MALE |
| 4. | Ethnicity: | NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN |
| 5. | Race: (Check X all that apply): | WHITE |
| 6. | Racial Designation: | |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Aug/31/2020 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

Form Comments

Inclusion Criteria Not Met

| | | |
|----|---|-------------------|
| 1. | Description of Inclusion Criterion Not Met | Not Done _____ |
|----|---|-------------------|

Exclusion Criteria Met

| | | |
|----|---|-------------------|
| 2. | Description of Exclusion Criterion Met | Not Done _____ |
|----|---|-------------------|

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Disposition - Screening

| | | |
|----|---|-------------|
| 1. | Date of Completion/Discontinuation /Death | Aug/31/2020 |
| 2. | Phase of Disposition: | SCREENING |
| 3. | Status: | COMPLETED |
| 4. | Specify Status: | [] |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Medical History Details

| | | |
|-----|--|-----------------------|
| 1.a | Line/MH Number: | [1] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Osteomyelitis] |
| | Start Date: | UNK/UNK/2018 |
| | Ongoing: | YES |
| 1.b | Line/MH Number: | [2] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Depressive disorder] |
| | Start Date: | May/8/2018 |
| | Ongoing: | YES |
| 1.c | Line/MH Number: | [3] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Hypogonadism] |
| | Start Date: | May/8/2018 |
| | Ongoing: | YES |
| 1.d | Line/MH Number: | [4] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Osteoarthritis] |
| | Start Date: | May/8/2018 |
| | Ongoing: | YES |
| 1.e | Line/MH Number: | [5] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Hyperlipidemia] |
| | Start Date: | May/8/2018 |
| | Ongoing: | YES |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

| | | |
|-----|--|----------------------|
| 1.f | Line/MH Number: | [6] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Hypertension] |
| | Start Date: | May/8/2018 |
| | Ongoing: | YES |
| 1.g | Line/MH Number: | [7] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [GOUT] |
| | Start Date: | May/8/2018 |
| | Ongoing: | YES |
| 1.h | Line/MH Number: | [8] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [OVERACTIVE BLADDER] |
| | Start Date: | Jul/1/2020 |
| | Ongoing: | YES |
| 1.i | Line/MH Number: | [9] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [GERD] |
| | Start Date: | May/30/2019 |
| | Ongoing: | YES |
| 1.j | Line/MH Number: | [10] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [BRONCHOSPASMS] |
| | Start Date: | May/31/2019 |
| | Ongoing: | YES |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

| | | |
|-----|--|-----------------|
| 1.k | Line/MH Number: | [11] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Muscle spasms] |
| | Start Date: | Jan/31/2020 |
| | Ongoing: | YES |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Vital Signs

| | | |
|----|------------------|-------------|
| 1. | Date: | Aug/31/2020 |
| 2. | Weight: | [274.0] |
| 3. | Unit: | LB |
| 4. | Height: | [77.0] |
| 5. | Unit: | in |
| 6. | Body Mass Index: | [32.5] |

Vital Signs Details

| | | |
|-----|-----------------------|-------------|
| 7.a | Record Identifier: | 1 |
| | Temperature: | [97.8] |
| | Unit: | F |
| | Temperature Location: | ORAL CAVITY |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Disposition

| | | |
|----|-----------------------|-------------|
| 1. | Randomization Date : | Aug/31/2020 |
| 2. | Randomization Number: | [246458] |
| 3. | Randomization Group: | [] |

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1097**Subject No:** 10971064**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:39[eCRF Audit Trail History](#)**Electronic Sample Tracking**

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Aug/31/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BN6BDJ] |
| 5.b | Sample ID | [BN6BDK] |
| 5.c | Sample ID | [BN6BDL] |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Aug/31/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BN69ZY] |
|-----|-----------|----------|

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Vaccination

| | | |
|-----|---|---|
| 1. | Was there a temporary delay of vaccination? | NO |
| 2. | Treatment Name | [BLINDED THERAPY] |
| 3. | Formulation: | INJECTION |
| 4. | Dose Date Time: | Aug/31/2020 11:16 |
| 5. | Anatomical Location: | DELTOID MUSCLE |
| 6. | Body Side: | LEFT |
| 7. | Route: | INTRAMUSCULAR |
| 8. | Actual Dose: | [] |
| 9. | Unit: | |
| 10. | Timeframe Subject Was Observed | THE PROTOCOL SPECIFIED OBSERVATION PERIOD |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? | YES |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Reactogenicity Diary

| | | |
|----|---|--|
| 1. | Select appropriate response - Reactogenicity diary collection | NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT |
|----|---|--|

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Sep/24/2020 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Vital Signs

| | | |
|----|-------|-------------|
| 1. | Date: | Sep/24/2020 |
|----|-------|-------------|

Vital Signs Details

| | | |
|-----|-----------------------|-------------|
| 2.a | Record Identifier: | 1 |
| | Temperature: | [98.9] |
| | Unit: | F |
| | Temperature Location: | ORAL CAVITY |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Sep/24/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BN6B5X] |
|-----|-----------|----------|

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Vaccination

| | | |
|-----|---|---|
| 1. | Was there a temporary delay of vaccination? | NO |
| 2. | Treatment Name | [BLINDED THERAPY] |
| 3. | Formulation: | INJECTION |
| 4. | Dose Date Time: | Sep/24/2020 09:27 |
| 5. | Anatomical Location: | DELTOID MUSCLE |
| 6. | Body Side: | LEFT |
| 7. | Route: | INTRAMUSCULAR |
| 8. | Actual Dose: | [] |
| 9. | Unit: | |
| 10. | Timeframe Subject Was Observed | THE PROTOCOL SPECIFIED OBSERVATION PERIOD |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? | YES |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Oct/27/2020 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Oct/27/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BL9XGD] |
| 5.b | Sample ID | [BL9XFK] |
| 5.c | Sample ID | [BPVCM3] |
| 5.d | Sample ID | [BPVC27] |
| 5.e | Sample ID | [BPVC28] |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

Date of Visit

| | | |
|----|-----------------|----|
| 1. | Date of Visit | // |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

Electronic Sample Tracking

| | | |
|----|--|-----|
| 1. | Data Origin | |
| 2. | Sample Type | |
| 3. | Sample Collected? | |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|----|-----------|-----|
| 5. | Sample ID | [] |
|----|-----------|-----|

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

Date of Visit

| | | |
|----|-----------------|----|
| 1. | Date of Visit | // |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

Electronic Sample Tracking

| | | |
|----|--|-----|
| 1. | Data Origin | |
| 2. | Sample Type | |
| 3. | Sample Collected? | |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|----|-----------|-----|
| 5. | Sample ID | [] |
|----|-----------|-----|

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

Date of Visit

| | | |
|----|-----------------|----|
| 1. | Date of Visit | // |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

Electronic Sample Tracking

| | | |
|----|--|-----|
| 1. | Data Origin | |
| 2. | Sample Type | |
| 3. | Sample Collected? | |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|----|-----------|-----|
| 5. | Sample ID | [] |
|----|-----------|-----|

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET
Feb/05/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Date of Visit

| | | | Comments |
|----|-----------------|------------|--------------------------|
| 1. | Date of Visit | Feb/5/2021 | |
| 2. | Erroneous Visit | | |

COVID-19 Illness Visit

| | | | |
|----|-------------------------|---------|--|
| 3. | COVID-19 Illness Visit: | COVID_A | |
|----|-------------------------|---------|--|

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
Feb/05/2021

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Signs and Symptoms

| | | |
|----|--------------------------------|------------|
| 1. | Date of Assessment: | Feb/5/2021 |
| 2. | Date of First Symptom Started: | Jan/4/2021 |
| 3. | Symptoms Ongoing? | YES |

Symptoms

| | | |
|-----|----------------------|--------------------------------------|
| 4.a | Symptoms: | FEVER |
| | Was symptom present? | NO |
| 4.b | Symptoms: | NEW OR INCREASED COUGH |
| | Was symptom present? | NO |
| 4.c | Symptoms: | NEW OR INCREASED SHORTNESS OF BREATH |
| | Was symptom present? | YES |
| 4.d | Symptoms: | CHILLS |
| | Was symptom present? | NO |
| 4.e | Symptoms: | NEW OR INCREASED MUSCLE PAIN |
| | Was symptom present? | NO |
| 4.f | Symptoms: | NEW LOSS OF TASTE OR SMELL |
| | Was symptom present? | NO |
| 4.g | Symptoms: | NEW OR INCREASED SORE THROAT |
| | Was symptom present? | NO |
| 4.h | Symptoms: | DIARRHEA |
| | Was symptom present? | NO |
| 4.i | Symptoms: | VOMITING |
| | Was symptom present? | NO |

Symptoms - Other

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
Feb/05/2021

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | |
|----|------------------------|-----|
| 5. | Symptoms - Other Text: | [] |
|----|------------------------|-----|

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| # | Date of Collection | Specimen Type | Specimen Collection Location | Assay Code and Description | Device Type | Form Instance |
|----|--------------------|---------------|------------------------------|----------------------------|-------------|---------------------------------|
| 1. | Not Done | Not Done | Not Done | Not Done | Not Done | Repeating Pages |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: MICROBIOLOGY SPECIMEN
Feb/05/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Microbiology Specimen

| | | | |
|----|-------------------------------|--------------------------|--------------------------|
| 1. | Actual Date of Collection: | Not Done _____ // | Comments |
| 2. | Specimen Type: | Not Done _____ | Comments |
| 3. | Specimen Collection Location: | Not Done _____ | Comments |
| 4. | Assay Code and Description: | Not Done _____ | Comments |
| 5. | Device Type: | Not Done _____ | Comments |
| 6. | Trade Name: | Not Done _____ | Comments |
| 7. | Test Result: | Not Done _____ | Comments |
| 8. | Comments/Findings/Details: | Not Done _____ [] | Comments |
| 9. | Trade Name Other, Specify: | Not Done _____ [] | Comments |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF
Feb/05/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|-----------------|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB_SELF |
| 3. | Sample Collected? | NO |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [done on site.] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BP2PZL] |
|-----|-----------|----------|

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
Feb/05/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|--|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Feb/5/2021 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BP2RZL] |
|-----|-----------|----------|

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION
Feb/05/2021**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971064**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[eCRF Audit Trail History](#)**Health Care Utilization**

| | | |
|-----|---------------------------------------|---|
| 1.a | Physician or Healthcare Professional: | SPECIALIST |
| | Occurrence of Visits or Contacts: | NO |
| 1.b | Physician or Healthcare Professional: | EMERGENCY ROOM |
| | Occurrence of Visits or Contacts: | YES Number of Visits or Contacts: [1] |
| 1.c | Physician or Healthcare Professional: | PRIMARY CARE PHYSICIAN |
| | Occurrence of Visits or Contacts: | NO |
| 1.d | Physician or Healthcare Professional: | URGENT CARE |
| | Occurrence of Visits or Contacts: | NO |
| 1.e | Physician or Healthcare Professional: | TELEPHONE CONSULTATION |
| | Occurrence of Visits or Contacts: | NO |
| 1.f | Physician or Healthcare Professional: | OTHER |
| | Occurrence of Visits or Contacts: | NO |

Health Care Utilization Other

| | | |
|----|-------------------------------------|-----|
| 2. | Other Type of Practitioner Specify: | [] |
|----|-------------------------------------|-----|

Health Care Utilization

| | | |
|----|--|----|
| 3. | Has the subject been hospitalized due to potential COVID-19 illness? | NO |
|----|--|----|

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| # | Treatment Identifier | Con Non-Drug Treatments Pre-specified | Treatment | Treatment | Start Date | Form Instance |
|----|----------------------|---------------------------------------|-----------|-----------|------------|---------------------------------|
| 1. | | | | | | Repeating Pages |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT
Feb/05/2021

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

Respiratory Treatment

| | | |
|----|---|-----|
| 1. | What is the treatment Identifier? | [] |
| 2. | Concomitant Non-drug Treatment Pre-specified: | |
| 3. | Treatment: | |
| 4. | Treatment: | [] |
| 5. | Start Date: | // |
| 6. | Ongoing? | |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS
Feb/05/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Illness Details

| | | |
|----|--|----------------------------|
| 1. | Category of Clinical Event: | POTENTIAL COVID-19 ILLNESS |
| 2. | Was a diagnosis obtained for Potential COVID-19 Illness? | NO |
| 3. | Toxicity Grade: | 3 |

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| # | Category of Clinical Event: | Subcategory of Clinical Event | Diagnosis Obtained | Toxicity Grade | Form Instance |
|----|-----------------------------|-------------------------------|--------------------|----------------|---------------------------------|
| 1. | | | | | Repeating Pages |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE
Feb/05/2021

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

Illness Details

| | | |
|----|--------------------------------|--|
| 1. | Category of Clinical Event: | |
| 2. | Subcategory of Clinical Event: | |
| 3. | Was a diagnosis obtained? | |
| 4. | Toxicity Grade: | |

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| # | Category for Lab Test | Vendor Name | Collection Date: | Specimen Type | Lab Result | | | Form Instance |
|----|-----------------------|-------------|------------------|---------------|-----------------------------------|---------------------------------|-----------------|---------------------------------|
| 1. | Not Done | Not Done | Not Done | Not Done | Sponsor-Defined Identifier | Test: | Result : | Repeating Pages |
| | | | | | Not Done | C Reactive Protein_PX329 | Not Done | |
| | | | | | Not Done | Alanine Aminotransferase_PX30 | Not Done | |
| | | | | | Not Done | Aspartate Aminotransferase_PX28 | Not Done | |
| | | | | | Not Done | Alkaline Phosphatase_PX35 | Not Done | |
| | | | | | Not Done | Bilirubin_PX21 | Not Done | |
| | | | | | Not Done | Blood Urea Nitrogen_PX47 | Not Done | |
| | | | | | Not Done | Creatinine_PX48 | Not Done | |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Feb/05/2021

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)
[Form Comments](#)
[eCRF Audit Trail History](#)

Lab Chemistry Details

| | | | |
|----|-----------------------------|--------------------------|--------------------------|
| 1. | Lab Panel: | Not Done _____ | Comments |
| 2. | Laboratory Name and Address | Not Done _____ [] | Comments |
| 3. | Collection Date: | Not Done _____ // | Comments |
| 4. | Specimen Type: | Not Done _____ | Comments |

Lab Result

| | | | |
|-----|-------------|--|--------------------------|
| 5.a | Sponsor ID: | Not Done _____ [] | Comments |
| | Test: | C Reactive Protein_PX329 | |
| | Result: | Not Done _____ [] | Comments |
| | Not Done: | Not Done _____ | Comments |
| | LNMT | Not Done _____ Low [] High [] Unit | Comments |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Feb/05/2021

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | |
|-----|-------------|--|--------------------------|
| 5.b | Sponsor ID: | Not Done _____ [] | Comments |
| | Test: | Alanine Aminotransferase_PX30 | |
| | Result: | Not Done _____ [] | Comments |
| | Not Done: | Not Done _____ | Comments |
| | LNMT | Not Done _____ Low [] High [] Unit | Comments |

| | | | |
|-----|-------------|--|--------------------------|
| 5.c | Sponsor ID: | Not Done _____ [] | Comments |
| | Test: | Aspartate Aminotransferase_PX28 | |
| | Result: | Not Done _____ [] | Comments |
| | Not Done: | Not Done _____ | Comments |
| | LNMT | Not Done _____ Low [] High [] Unit | Comments |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Feb/05/2021

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | |
|-----|-------------|--|--------------------------|
| 5.d | Sponsor ID: | Not Done _____ [] | Comments |
| | Test: | Alkaline Phosphatase_PX35 | |
| | Result: | Not Done _____ [] | Comments |
| | Not Done: | Not Done _____ | Comments |
| | LNMT | Not Done _____ Low [] High [] Unit | Comments |

| | | | |
|-----|-------------|--|--------------------------|
| 5.e | Sponsor ID: | Not Done _____ [] | Comments |
| | Test: | Bilirubin_PX21 | |
| | Result: | Not Done _____ [] | Comments |
| | Not Done: | Not Done _____ | Comments |
| | LNMT | Not Done _____ Low [] High [] Unit | Comments |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Feb/05/2021

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | |
|-----|-------------|--|--------------------------|
| 5 f | Sponsor ID: | Not Done _____ [] | Comments |
| | Test: | Blood Urea Nitrogen_PX47 | |
| | Result: | Not Done _____ [] | Comments |
| | Not Done: | Not Done _____ | Comments |
| | LNMT | Not Done _____ Low [] High [] Unit | Comments |

| | | | |
|-----|-------------|--|--------------------------|
| 5.g | Sponsor ID: | Not Done _____ [] | Comments |
| | Test: | Creatinine_PX48 | |
| | Result: | Not Done _____ [] | Comments |
| | Not Done: | Not Done _____ | Comments |
| | LNMT | Not Done _____ Low [] High [] Unit | Comments |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| # | Category for Lab Test | Vendor Name (DERIVED) | Collection Date: | Specimen Type | Lab Result | | | Form Instance |
|----|-----------------------|-----------------------|------------------|---------------|----------------------------|-------|---------|---------------------------------|
| 1. | | | | | Sponsor-Defined Identifier | Test: | Result: | Repeating Pages |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Feb/05/2021

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

Laboratory Data Hematology

| | | |
|----|-----------------------------|-----|
| 1. | Lab Panel: | |
| 2. | Laboratory Name and Address | [] |
| 3. | Collection Date: | // |
| 4. | Specimen Type: | |

Lab Result

| | | |
|----|-------------|-----------------------------------|
| 5. | Sponsor ID: | [] |
| | Test: | |
| | Result: | [] |
| | Not Done: | |
| | LNMT | Low [] High [] Unit |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| # | Date: | Vital Signs Details | | | Form Instance |
|----|-------|---------------------------|------------------|-------------------|---------------------------------|
| 1. | | Record Identifier: | Systolic: | Diastolic: | Repeating Pages |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID
Feb/05/2021

Form Version: 21-Aug-2020 02:50

Form Status: Not Started

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

Vital Signs

| | | |
|----|-------|----|
| 1. | Date: | // |
|----|-------|----|

Vital Signs Details

| | | |
|----|--|-----|
| 2. | Record Identifier: | |
| | Systolic: | [] |
| | Diastolic: | [] |
| | Respiratory Rate in respirations/minute: | [] |
| | Heart Rate in beats/minute: | [] |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| # | Date: | Vital Signs Details | Form Instance | | |
|--------------------|-------------------|--|--------------------|-------------------|---------------------------------|
| 1. | | <table border="1"><tr><td>Record Identifier:</td><td>Oxygen Saturation</td></tr></table> | Record Identifier: | Oxygen Saturation | Repeating Pages |
| Record Identifier: | Oxygen Saturation | | | | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR
Feb/05/2021

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

Vital Signs

| | | |
|----|-------|----|
| 1. | Date: | // |
|----|-------|----|

Vital Signs Details

| | | |
|----|-----------------------|-----|
| 2. | Record Identifier: | |
| | SPO2 Pulse Oximetry % | [] |

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| # | Date Time of Assessment | Arterial Blood Gases PaO2 | FiO2 (Fraction of Inhaled Oxygen) | Form Instance |
|----|-------------------------|---------------------------|-----------------------------------|---------------------------------|
| 1. | | | | Repeating Pages |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** OXYGENATION PARAMETERS
Feb/05/2021

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

Oxygenation Parameters

| | | |
|----|------------------------------------|-----|
| 1. | Date Time of Assessment: | // |
| 2. | Arterial Blood Gases PaO2 (mmHg): | [] |
| 3. | FiO2 (Fraction of Inhaled Oxygen): | [] |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| # | Sponsor-Defined Identifier | Category for Medication | Concomitant Medications Pre-specified | Name of Medication | Start Date | Form Instance |
|----|----------------------------|-------------------------|---------------------------------------|--------------------|------------|---------------------------------|
| 1. | | | | | | Repeating Pages |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
Feb/05/2021

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

Concomitant Medications

| | | |
|----|---|-----|
| 1. | What is the medication identifier? | [] |
| 2. | Category: | |
| 3. | Concomitant Medications Pre-specified: | |
| 4. | Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation). | [] |
| 5. | Start Date: | // |
| 6. | Ongoing? | |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| # | Date of Assessment | Location of Assessment | Imaging Method | Overall Assessment | Form Instance |
|----|--------------------|------------------------|----------------|--------------------|---------------------------------|
| 1. | | | | | Repeating Pages |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING
Feb/05/2021

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

Imaging

| | | |
|----|-------------------------|----|
| 1. | Date of Assessment: | // |
| 2. | Location of Assessment: | |
| 3. | Type of Imaging Exam: | |
| 4. | Assessment: | |

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Mar/08/2021

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|------------|
| 1. | Date of Visit | Mar/8/2021 |
| 2. | Erroneous Visit | |

COVID-19 Illness Visit

| | | |
|----|-------------------------|----------|
| 3. | COVID-19 Illness Visit: | COVID_A1 |
|----|-------------------------|----------|

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Mar/08/2021

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|--|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Mar/8/2021 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BP2S2S] |
| 5.b | Sample ID | [BP2S2T] |
| 5.c | Sample ID | [BP2S2V] |
| 5.d | Sample ID | [BPN9RV] |
| 5.e | Sample ID | [BPN9RW] |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Date of Visit

| | | |
|----|-----------------|----|
| 1. | Date of Visit | // |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Unplanned Assessments

| | | |
|----|-------------|--|
| 1. | Assessments | |
|----|-------------|--|

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Disposition - Treatment

| | | |
|----|---|-------------|
| 1. | Date of Completion/Discontinuation /Death : | Oct/27/2020 |
| 2. | Phase of Disposition: | VACCINATION |
| 3. | Status: | COMPLETED |
| 4. | Specify Status: | [] |

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

Disposition - Follow-Up

| | | |
|----|---|-----|
| 1. | Date of Completion/Discontinuation /Death : | // |
| 2. | Phase of Disposition: | |
| 3. | Status: | |
| 4. | Specify Status: | [] |

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Date of Visit

| | | |
|----|-----------------|----|
| 1. | Date of Visit | // |
| 2. | Erroneous Visit | |

COVID-19 Repeat Swab

| | | |
|----|-----------------------|--|
| 3. | COVID-19 Repeat Swab: | |
|----|-----------------------|--|

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Electronic Sample Tracking

| | | |
|----|--|-----|
| 1. | Data Origin | |
| 2. | Sample Type | |
| 3. | Sample Collected? | |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|----|-----------|-----|
| 5. | Sample ID | [] |
|----|-----------|-----|

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| # | Category | AE Identifier | Adverse Event | Start Date | Is the Adverse Event Still Ongoing | Form Instance |
|----|---------------|---------------|--------------------------------|----------------------|---|---------------------------------|
| 1. | ADVERSE EVENT | 1 | Persistent Atrial Fibrillation | Jan/21/2021 UNK: UNK | YES | Repeating Pages |
| 2. | ADVERSE EVENT | 2 | NEW ONSET ATRIAL FIB | Jan/4/2021 UNK: UNK | NO End Date Time: Jan/6/2021 UNK: UNK | Repeating Pages |
| 3. | ADVERSE EVENT | 3 | congestive heart failure | Dec/22/2020 UNK: UNK | YES | Repeating Pages |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Not Complete

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

| | | |
|----|---|---|
| 1. | Category: | ADVERSE EVENT |
| 2. | AE ID: | [1] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [Persistent Atrial Fibrillation] |
| 4. | Start Date Time: | Jan/21/2021 UNK:UNK |
| 5. | Is the adverse event still ongoing? | YES |
| 6. | Toxicity Grade: | 3 |
| 7. | Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). | YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO |
| 8. | Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log. | NO |
| 9. | Is this event related to study treatment: | NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unknown] |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Not Complete

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

| | | |
|-----|--|----------------------|
| 10. | Latest Action Taken with Study Treatment: | NOT APPLICABLE |
| 11. | Was a Concomitant Medication given? | YES |
| 12. | Was a Non-Drug Treatment given? | YES |
| 13. | What was the outcome of this adverse event?: | RECOVERING/RESOLVING |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | NO |
| 15. | Serious Adverse Event Number: For Pfizer Use Only | [2021078077] |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

| | | |
|----|---|---|
| 1. | Category: | ADVERSE EVENT |
| 2. | AE ID: | [2] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [NEW ONSET ATRIAL FIB] |
| 4. | Start Date Time: | Jan/4/2021 UNK:UNK |
| 5. | Is the adverse event still ongoing? | NO End Date Time: Jan/6/2021 UNK:UNK |
| 6. | Toxicity Grade: | 3 |
| 7. | Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). | YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO |
| 8. | Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log. | NO |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

| | | |
|-----|--|--|
| 9. | Is this event related to study treatment: | NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unknown] |
| 10. | Latest Action Taken with Study Treatment: | NOT APPLICABLE |
| 11. | Was a Concomitant Medication given? | YES |
| 12. | Was a Non-Drug Treatment given? | NO |
| 13. | What was the outcome of this adverse event?: | RECOVERED/RESOLVED |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | NO |
| 15. | Serious Adverse Event Number: For Pfizer Use Only | [2021113850] |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

| | | |
|-----|---|--|
| 1. | Category: | ADVERSE EVENT |
| 2. | AE ID: | [3] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [congestive heart failure] |
| 4. | Start Date Time: | Dec/22/2020 UNK:UNK |
| 5. | Is the adverse event still ongoing? | YES |
| 6. | Toxicity Grade: | 2 |
| 7. | Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). | NO |
| 8. | Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log. | NO |
| 9. | Is this event related to study treatment: | NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [fluid retention] |
| 10. | Latest Action Taken with Study Treatment: | NOT APPLICABLE |
| 11. | Was a Concomitant Medication given? | YES |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

| | | |
|-----|--|----------------------|
| 12. | Was a Non-Drug Treatment given? | NO |
| 13. | What was the outcome of this adverse event?: | RECOVERING/RESOLVING |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | NO |
| 15. | Serious Adverse Event Number: For Pfizer Use Only | [] |

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| # | Category | Medication Error | Start Date | Is the medication error Still On going | Study Medication Errors Action | Form Instance |
|----|----------|------------------|------------|--|--------------------------------|---------------------------------|
| 1. | | | | | | Repeating Pages |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

Medication Error

| | | |
|-----|---|-----|
| 1. | Category: | |
| 2. | Medication Error (Type of Medication Error): | [] |
| 3. | Start Date: | // |
| 4. | Is the medication error still ongoing? | |
| 5. | Latest Action Taken with Study Treatment: | |
| 6. | Was a Concomitant Medication given? | |
| 7. | Was a Non-Drug Treatment given? | |
| 8. | Did the Medication Error cause the subject to be discontinued from the study? | |
| 9. | Was this medication error associated with any adverse events? | |
| 10. | Serious Adverse Event Number: For Pfizer Use Only | [] |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| # | Sponsor-Defined Identifier | Category for Medication | Concomitant Medications Pre-specified | Name of Medication | Start Date | Form Instance |
|----|----------------------------|-------------------------|---------------------------------------|--------------------|------------|---------------------------------|
| 1. | | | | | | Repeating Pages |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

Concomitant Medications

| | | |
|----|---|-----|
| 1. | What is the medication identifier? | [] |
| 2. | Category: | |
| 3. | Concomitant Medications Pre-specified: | |
| 4. | Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation). | [] |
| 5. | Date: | // |

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| # | Sponsor-Defined Identifier | Category for Medication | Concomitant Medications Pre-specified | Name of Medication | Dose Description | Form Instance |
|----|----------------------------|-------------------------|---------------------------------------|--------------------|------------------|---------------------------------|
| 1. | | | | | | Repeating Pages |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

Concomitant Medications

| | | |
|-----|---|-----|
| 1. | What is the medication identifier? | [] |
| 2. | Category: | |
| 3. | Concomitant Medications Pre-specified: | |
| 4. | Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation). | [] |
| 5. | Dose: | [] |
| 6. | Dose Unit: | |
| 7. | Dose Frequency: | |
| 8. | Route: | |
| 9. | Start Date: | // |
| 10. | Ongoing? | |

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| # | Category | Treatment Identifier | Con Non-Drug Treatments Pre-specified | Treatment | Start Date | Form Instance |
|----|----------|----------------------|---------------------------------------|-----------|------------|---------------------------------|
| 1. | | | | | | Repeating Pages |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

Radiation Treatment

| | | |
|----|---|-----|
| 1. | Category: | |
| 2. | What is the treatment Identifier? | [] |
| 3. | Concomitant Non-drug Treatment Pre-specified: | |
| 4. | Treatment: | [] |
| 5. | Start Date: | // |
| 6. | Ongoing? | |

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| # | Transfusion Type | Date of Transfusion | Form Instance |
|----|------------------|---------------------|---------------------------------|
| 1. | | | Repeating Pages |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| | | |
|----|----------------------|----|
| 1. | Transfusion Type: | |
| 2. | Date of Transfusion: | // |

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Date of Visit

| | | |
|----|-----------------|----|
| 1. | Date of Visit | // |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VITAL SIGNS - TEMP

Form Version: 20-Feb-2021 02:16

Form Status: Not Started

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Vital Signs

| | | |
|----|-------|----|
| 1. | Date: | // |
|----|-------|----|

Vital Signs Details

| | | |
|----|-----------------------|-----|
| 2. | Record Identifier: | |
| | Temperature: | [] |
| | Unit: | |
| | Temperature Location: | |

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Vaccination

| | | |
|-----|---|-----|
| 1. | Was there a temporary delay of vaccination? | |
| 2. | Treatment Name | [] |
| 3. | Formulation: | |
| 4. | Dose Date Time: | // |
| 5. | Anatomical Location: | |
| 6. | Body Side: | |
| 7. | Route: | |
| 8. | Actual Dose: | [] |
| 9. | Unit: | |
| 10. | Timeframe Subject Was Observed | |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? | |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Contact Outcome

| | | |
|----|-------------------|-----|
| 1. | Contact Type: | |
| 2. | Was contact made? | |
| 3. | Comments: | [] |

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01

Form Status: Not Started

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Contact Outcome

| | | |
|----|-------------------|-----|
| 1. | Contact Type: | |
| 2. | Was contact made? | |
| 3. | Comments: | [] |

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Date of Visit

| | | |
|----|-----------------|----|
| 1. | Date of Visit | // |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Informed Consent - Asymptomatic Surveillance

| | | |
|----|--------------|--|
| 1. | Consent Was: | |
|----|--------------|--|

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Electronic Sample Tracking

| | | |
|----|--|-----|
| 1. | Data Origin | |
| 2. | Sample Type | |
| 3. | Sample Collected? | |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|----|-----------|-----|
| 5. | Sample ID | [] |
|----|-----------|-----|

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Electronic Sample Tracking

| | | |
|----|--|-----|
| 1. | Data Origin | |
| 2. | Sample Type | |
| 3. | Sample Collected? | |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|----|-----------|-----|
| 5. | Sample ID | [] |
|----|-----------|-----|

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Jan/14/2021 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

| | | |
|----|---|--|
| 1. | Select appropriate response - Is participant willing to return for Vaccination 3? | Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2 |
|----|---|--|

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Treatment Unblinded

| | | |
|----|--------------------------------|---|
| 1. | Date Treatment Unblinded : | Jan/14/2021 |
| 2. | Primary Reason for Unblinding: | ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION |

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Withdrawal Of Consent

| | | |
|----|------------------------------|----|
| 1. | Withdrawal of Consent Date : | // |
|----|------------------------------|----|

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Death Details

| | | |
|----|---|----|
| 1. | Date of Collection / Notification of Death: | // |
|----|---|----|

Cause of Death

| | | |
|----|------------------------|-----|
| 2. | Cause of Death Status: | |
| | Cause of Death: | [] |

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Subject Status

| | | |
|----|---------------------|-------------|
| 1. | Subject Status | FOLLOW-UP |
| 2. | Subject Status Date | Oct/27/2020 |

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Casebook Signature Form

| | | |
|----|--------------------|----------------------|
| 1. | Casebook Signature | Click Here to Enable |
|----|--------------------|----------------------|

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Audit Trail](#)

This form requires signing by a member of each of the following signature groups:

- CRF_Sign

| Name | Signature Meaning | Date | Type | Action |
|-----------------|-------------------|---|------|--------|
| Tom Christensen | Approved | Mar-09-2021 14:24:00 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |

Affidavit:

By my dated signature below, I, TomChristensen, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|------------------------|
| Form | Sep-02-2020 09:05:18 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Incomplete Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: DATE OF VISIT - ILLNESS ONSET - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|--|
| 1 | Feb-10-2021 09:45:51 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | swab done at site, no other testing done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Feb/05/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|--|---------------------|--|
| Form | Feb-11-2021 13:49:55 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Done |
| Form | Feb-10-2021 09:39:35 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | There are no records of COVID testing. |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Feb/05/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|--|---------------------|----------|
| 1 | Feb-11-2021 13:49:55 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Feb/05/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|--|---------------------|----------|
| 2 | Feb-11-2021 13:49:55 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Feb/05/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|--|---------------------|----------|
| 3 | Feb-11-2021 13:49:55 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Feb/05/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|--|---------------------|----------|
| 4 | Feb-11-2021 13:49:55 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Feb/05/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|--|---------------------|----------|
| 5 | Feb-11-2021 13:49:55 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Feb/05/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|--|---------------------|----------|
| 6 | Feb-11-2021 13:49:55 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Feb/05/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|--|---------------------|----------|
| 7 | Feb-11-2021 13:49:55 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Feb/05/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|--|---------------------|----------|
| 8 | Feb-11-2021 13:49:55 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Feb/05/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|--|---------------------|----------|
| 9 | Feb-11-2021 13:49:55 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/05/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|-----------------------------------|
| Form | Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | no local testing done Not Done |
| Form | Feb-10-2021 09:46:55 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | no local testing done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/05/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|-----------------------------------|
| 1 | Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | no local testing done Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/05/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|-----------------------------------|
| 2 | Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | no local testing done Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/05/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|-----------------------------------|
| 3 | Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | no local testing done Not Done |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/05/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|-----------------------------------|
| 4 | Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | no local testing done Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/05/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|-----------------------------------|
| 5.a | Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | no local testing done Not Done |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/05/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|-----------------------|
| 5.a | Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | no local testing done |
| | | | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/05/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|-----------------------|
| 5.a | Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | no local testing done |
| | | | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/05/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|-----------------------|
| 5.a | Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | no local testing done |
| | | | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/05/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|-----------------------------------|
| 5.b | Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | no local testing done Not Done |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/05/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|-----------------------------------|
| 5.b | Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | no local testing done Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/05/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|-----------------------------------|
| 5.b | Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | no local testing done Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/05/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|-----------------------------------|
| 5.b | Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | no local testing done Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/05/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|-----------------------------------|
| 5.c | Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | no local testing done Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/05/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|-----------------------------------|
| 5.c | Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | no local testing done Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/05/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|-----------------------------------|
| 5.c | Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | no local testing done Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/05/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|-----------------------------------|
| 5.c | Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | no local testing done Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/05/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|-----------------------------------|
| 5.d | Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | no local testing done Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/05/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|-----------------------------------|
| 5.d | Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | no local testing done Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/05/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|-----------------------------------|
| 5.d | Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | no local testing done Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/05/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|-----------------------------------|
| 5.d | Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | no local testing done Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/05/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|-----------------------------------|
| 5.e | Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | no local testing done Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/05/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|-----------------------------------|
| 5.e | Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | no local testing done Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/05/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|-----------------------------------|
| 5.e | Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | no local testing done Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/05/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|-----------------------------------|
| 5.e | Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | no local testing done Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/05/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|-----------------------------------|
| 5 f | Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | no local testing done Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/05/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|-----------------------|
| 5 f | Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | no local testing done |
| | | | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/05/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|-----------------------------------|
| 5 f | Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | no local testing done Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/05/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|-----------------------------------|
| 5 f | Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | no local testing done Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/05/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|-----------------------|
| 5.g | Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | no local testing done |
| | | | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/05/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|-----------------------|
| 5.g | Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | no local testing done |
| | | | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/05/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|-----------------------------------|
| 5.g | Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | no local testing done Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/05/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|-----------------------------------|
| 5.g | Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | no local testing done Not Done |

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

This form requires signing by a member of each of the following signature groups:

- CRF_Sign

| Name | Signature Meaning | Date | Type | Action |
|-----------------|-------------------|---|------|--------|
| Tom Christensen | Approved | Mar-09-2021 14:24:00 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |

Affidavit:

By my dated signature below, I, TomChristensen, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

| | | | | |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Mar-09-2021 11:12:12 (UTC-05:00) Eastern Time (US & Canada) | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|-----------------|----------|---|------|--------|
| Tom Christensen | Approved | Mar-09-2021 07:44:19 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |
|-----------------|----------|---|------|--------|

Affidavit:

By my dated signature below, I, TomChristensen, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

| | | | | |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Mar-03-2021 09:05:28 (UTC-05:00) Eastern Time (US & Canada) | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|-----------------|----------|---|------|--------|
| Tom Christensen | Approved | Mar-02-2021 12:17:37 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |
|-----------------|----------|---|------|--------|

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001**Visit:** Investigator Signature - Unscheduled**Form:** CASEBOOK SIGNATURE FORM - Signature History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Signed, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971064**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39**Affidavit:**

By my dated signature below, I, TomChristensen, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

| | | | | |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Feb-25-2021 09:38:22 (UTC-05:00) Eastern Time (US & Canada) | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|-----------------|----------|---|------|--------|
| Tom Christensen | Approved | Feb-24-2021 19:08:03 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |
|-----------------|----------|---|------|--------|

Affidavit:

By my dated signature below, I, TomChristensen, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

| | | | | |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Feb-01-2021 08:41:43 (UTC-05:00) Eastern Time (US & Canada) | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|-----------------|----------|---|------|--------|
| Tom Christensen | Approved | Jan-20-2021 20:49:22 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |
|-----------------|----------|---|------|--------|

Affidavit:

By my dated signature below, I, TomChristensen, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Jan-20-2021 16:47:50 (UTC-05:00) Eastern Time (US & Canada) | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|-----------------|----------|---|------|--------|
| Tom Christensen | Approved | Nov-02-2020 20:12:47 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |
|-----------------|----------|---|------|--------|

Affidavit:

By my dated signature below, I, TomChristensen, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

1. Select appropriate response - Protocol version

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-02-2020 09:03:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 24 JUL 2020 | Initial Entry |

2. Select appropriate response - What cohort does the subject belong to?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------------------|---------------|
| Sep-02-2020 09:03:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: STAGE 3 COHORTS | Initial Entry |

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

I. Consent Was:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-02-2020 09:04:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: OBTAINED Date Written Consent Obtained Aug/31/2020 | Initial Entry |

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

1. Subject ID

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------|-----------------------------------|
| Sep-02-2020 09:03:45 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 10971064 | Item copied from previous form |

2. Birth Date:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|------------------------------------|------------------|
| Sep-02-2020 09:03:42 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: (b) (6) 1942 | Enrollment Entry |

3. Sex:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------|---------------|
| Sep-02-2020 09:04:40 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: MALE | Initial Entry |

4. Ethnicity:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-02-2020 09:04:40 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN | Initial Entry |

5. Race: (Check X all that apply):

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------|---------------|
| Sep-02-2020 09:04:40 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: WHITE | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|--|
| Oct-03-2020 08:38:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Oct-02-2020 10:47:10 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Because there was no COVID illness |
| Oct-01-2020 12:04:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | As per Illness edary records, subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 14SEP2020. But there is no COVID Illness visit reported in the database. Please clarify. |
| Sep-02-2020 09:05:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/31/2020 | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-02-2020 09:06:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/31/2020 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Sep-02-2020 09:06:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SCREENING | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------------|---------------|
| Sep-02-2020 09:06:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

1.a

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Sep-02-2020 13:20:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 1 Medical History Term: Osteomyelitis Start Date: UNK/UNK/2018 Ongoing: YES | Initial Entry |

1.a Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-02-2020 13:20:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 1 | Initial Entry |

1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------------------|---------------|
| Sep-02-2020 13:20:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Osteomyelitis | Initial Entry |

1.a Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Sep-02-2020 13:20:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/2018 | Initial Entry |

1.a Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Sep-02-2020 13:20:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

1.b

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Sep-02-2020 13:20:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Line/MH Number 2 : Medical History T Depressive disorder: Start Date: May/8/2018 Ongoing: YES | Initial Entry |

1.b Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-02-2020 13:20:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 2 | Initial Entry |

1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-02-2020 13:20:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Depressive disorder | Initial Entry |

1.b Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|---------------|
| Sep-02-2020 13:20:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> May/8/2018 | Initial Entry |

1.b Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Sep-02-2020 13:20:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> YES | Initial Entry |

1.c

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Sep-02-2020 13:21:21 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Line/MH Number: 3 | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

| | | | |
|--|--|--|---|
| | | | Medical History Term: Hypogonadism Start Date: May/8/2018 Ongoing: YES |
|--|--|--|---|

1.c Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-02-2020 13:21:21 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 3 | Initial Entry |

1.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Sep-02-2020 13:21:21 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Hypogonadism | Initial Entry |

1.c Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|---------------|
| Sep-02-2020 13:21:21 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: May/8/2018 | Initial Entry |

1.c Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Sep-02-2020 13:21:21 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

1.d

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Sep-02-2020 13:22:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 4 Medical History Term: Osteoarthritis Start Date: May/8/2018 Ongoing: YES | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

1.d Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-02-2020 13:22:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 4 | Initial Entry |

1.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Sep-02-2020 13:22:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Osteoarthritis | Initial Entry |

1.d Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|---------------|
| Sep-02-2020 13:22:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: May/8/2018 | Initial Entry |

1.d Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Sep-02-2020 13:22:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

1.e

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Sep-02-2020 13:22:49 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 5 Medical History Term: Hyperlipidemia Start Date: May/8/2018 Ongoing: YES | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

1.e Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-02-2020 13:22:49 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 5 | Initial Entry |

1.e Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Sep-02-2020 13:22:49 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Hyperlipidemia | Initial Entry |

1.e Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|---------------|
| Sep-02-2020 13:22:49 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: May/8/2018 | Initial Entry |

1.e Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Sep-02-2020 13:22:49 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

1.f

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Sep-02-2020 13:23:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 6 Medical History Term: Hypertension Start Date: May/8/2018 Ongoing: YES | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

1.f Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-02-2020 13:23:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 6 | Initial Entry |

1.f Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Sep-02-2020 13:23:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Hypertension | Initial Entry |

1.f Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|---------------|
| Sep-02-2020 13:23:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: May/8/2018 | Initial Entry |

1.f Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Sep-02-2020 13:23:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

1.g

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Mar-02-2021 09:54:30 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 7 Medical History Term GOUT : Start Date: May/8/2018 Ongoing: YES | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

1.g Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Mar-02-2021 09:54:30 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 7 | Initial Entry |

1.g Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------|---------------|
| Mar-02-2021 09:54:30 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: GOUT | Initial Entry |

1.g Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|---------------|
| Mar-02-2021 09:54:30 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: May/8/2018 | Initial Entry |

1.g Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Mar-02-2021 09:54:30 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

1.h

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Mar-02-2021 09:55:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Num 8 ber: Medical Histor OVERACTIVE B y Term: LADDER Start Date: Jul/1/2020 Ongoing: YES | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

1.h Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Mar-02-2021 09:55:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 8 | Initial Entry |

1.h Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Mar-02-2021 09:55:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: OVERACTIVE BLADDER | Initial Entry |

1.h Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|---------------|
| Mar-02-2021 09:55:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jul/1/2020 | Initial Entry |

1.h Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Mar-02-2021 09:55:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

1.i

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Mar-02-2021 09:55:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 9 Medical History Term: GERD Start Date: May/30/2019 Ongoing: YES | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

1.i Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Mar-02-2021 09:55:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 9 | Initial Entry |

1.i Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------|---------------|
| Mar-02-2021 09:55:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: GERD | Initial Entry |

1.i Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Mar-02-2021 09:55:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: May/30/2019 | Initial Entry |

1.i Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Mar-02-2021 09:55:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

1.j

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Mar-02-2021 09:56:14 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Numbe 10 r: Medical History BRONCHOSPA Term: SMS Start Date: May/31/2019 Ongoing: YES | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

1.j Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------|---------------|
| Mar-02-2021 09:56:14 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 10 | Initial Entry |

1.j Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------------------|---------------|
| Mar-02-2021 09:56:14 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BRONCHOSPASMS | Initial Entry |

1.j Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Mar-02-2021 09:56:14 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: May/31/2019 | Initial Entry |

1.j Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Mar-02-2021 09:56:14 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| <i>1.k</i> | | | | |
|---|-----------------|-------------------------|--|---------------|
| Date | Location | User | Value | Reason |
| Mar-03-2021 11:20:09 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 11 Medical History Term: Muscle spasms Start Date: Jan/31/2020 Ongoing: YES | Initial Entry |

| <i>1.k Line/MH Number:</i> | | | | |
|---|-----------------|-------------------------|--------------------------|---------------|
| Date | Location | User | Value | Reason |
| Mar-03-2021 11:20:09 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 11 | Initial Entry |

| <i>1.k Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:</i> | | | | |
|--|-----------------|---------------------|-------------------------------------|---------------|
| Date | Location | User | Value | Reason |
| Mar-03-2021 11:20:09 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Muscle spasms | Initial Entry |

| <i>1.k Start Date:</i> | | | | |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Date | Location | User | Value | Reason |
| Mar-03-2021 11:20:09 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/31/2020 | Initial Entry |

| <i>1.k Ongoing:</i> | | | | |
|---|-----------------|---------------------|---------------------------|---------------|
| Date | Location | User | Value | Reason |
| Mar-03-2021 11:20:09 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

1. Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-02-2020 09:07:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/31/2020 | Initial Entry |

2. Weight:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------|---------------|
| Sep-02-2020 09:07:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 274.0 | Initial Entry |

3. Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Sep-02-2020 09:07:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: LB | Initial Entry |

4. Height:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------|---------------|
| Sep-02-2020 09:07:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 77.0 | Initial Entry |

5. Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Sep-02-2020 09:07:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: in | Initial Entry |

6. Body Mass Index:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Sep-02-2020 09:07:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 32.5 | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

7.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-02-2020 09:07:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier:: 1 Temperature: 97.8 Temperature Unit: F Temperature Locat ORAL CAVI ion:: TY | Initial Entry |

7.a Record Identifier:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Sep-02-2020 09:07:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

7.a Temperature:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------|---------------|
| Sep-02-2020 09:07:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 97.8 | Initial Entry |

7.a Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Sep-02-2020 09:07:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: F | Initial Entry |

7.a Temperature Location:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-02-2020 09:07:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ORAL CAVITY | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

1. Randomization Date :

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-02-2020 13:17:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/31/2020 | Initial Entry |

2. Randomization Number:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Sep-02-2020 13:17:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 246458 | Initial Entry |

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971064**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Data Origin**

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Sep-03-2020 16:06:59 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Sep-03-2020 16:06:59 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|---|
| Sep-03-2020 16:07:14 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Sep-03-2020 16:06:59 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Sep-03-2020 16:06:59 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Aug/31/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-03-2020 16:07:14 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BN6BDJ | Initial Entry |

5.a Sample ID

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Sep-03-2020 16:07:14 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BN6BDJ | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Sep-03-2020 16:07:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sample ID: BN6BDK | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Sep-03-2020 16:07:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BN6BDK | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Sep-03-2020 16:07:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sample ID: BN6BDL | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Sep-03-2020 16:07:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BN6BDL | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971064**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Data Origin**

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Sep-03-2020 16:08:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Sep-03-2020 16:08:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|---|
| Sep-03-2020 16:08:32 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Sep-03-2020 16:08:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Sep-03-2020 16:08:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Aug/31/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-03-2020 16:08:32 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BN69ZY | Initial Entry |

5.a Sample ID

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Sep-03-2020 16:08:32 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BN69ZY | Initial Entry |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-02-2020 13:18:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

2. Treatment Name

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------------------|---------------|
| Sep-02-2020 13:18:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> BLINDED THERAPY | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Sep-02-2020 13:18:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> INJECTION | Initial Entry |

4. Dose Date Time:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Sep-02-2020 13:18:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Aug/31/2020 11:16 | Initial Entry |

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------------------|---------------|
| Sep-02-2020 13:18:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> DELTOID MUSCLE | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------|---------------|
| Sep-02-2020 13:18:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> LEFT | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

7. Route:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Sep-02-2020 13:18:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Sep-02-2020 13:18:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: THE PROTOCOL SPECIFIED OBS ERVATION PERIOD | Initial Entry |

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Sep-02-2020 13:18:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

1. Select appropriate response - Reactogenicity diary collection

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--|--|
| Sep-07-2020 06:01:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Sep-05-2020 14:51:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Transcription Error |
| Sep-05-2020 14:51:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO - REACTOGENICITY E- DIARY NOT COLLECTED F OR THIS SUBJECT | Transcription Error |
| Sep-04-2020 06:27:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Sagaya Mythili (b) (4) | Query 1: Opened | eDiary: REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT is 'Yes' however VAX 1 eDiary records are not available for the subject. Please verify and update. Else, confirm in query response appropriately. |
| Sep-02-2020 09:07:51 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES - REACTOGENICITY E- DIARY COLLECTED FOR T HIS SUBJECT | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|--|
| Sep-28-2020 06:04:49 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | As per site confirmation - PD tracker updated |
| Sep-25-2020 13:47:08 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | The patient missed the scheduled appointment and came 1 day later. |
| Sep-25-2020 05:01:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | PDQ: DOV at this visit is out of window (1 day) from DOV (31/Aug /2020) at V1D1VX1L. Please either update DOV or confirm whether visit is out of window due to temporary delay of vaccination/ else provide details as appropriate. |
| Sep-24-2020 16:55:44 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/24/2020 | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

1. Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-24-2020 16:56:21 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/24/2020 | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-24-2020 16:56:21 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier:: 1 Temperature: 98.9 Temperature Unit: F Temperature Location:: ORAL CAVITY | Initial Entry |

2.a Record Identifier:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Sep-24-2020 16:56:21 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

2.a Temperature:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------|---------------|
| Sep-24-2020 16:56:21 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 98.9 | Initial Entry |

2.a Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Sep-24-2020 16:56:21 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: F | Initial Entry |

2.a Temperature Location:

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-24-2020 16:56:21 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ORAL CAVITY | Initial Entry |
|---|-----------------|---------------------|-----------------------------------|---------------|

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Sep-24-2020 16:56:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Sep-24-2020 16:56:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|---|
| Sep-24-2020 16:57:08 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Sep-24-2020 16:56:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Sep-24-2020 16:56:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Sep/24/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-24-2020 16:57:08 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BN6B5X | Initial Entry |

5.a Sample ID

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Sep-24-2020 16:57:08 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BN6B5X | Initial Entry |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Sep-24-2020 16:58:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2. Treatment Name

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Sep-24-2020 16:58:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BLINDED THERAPY | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Sep-24-2020 16:58:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INJECTION | Initial Entry |

4. Dose Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-24-2020 16:58:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/24/2020 09:27 | Initial Entry |

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Sep-24-2020 16:58:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------|---------------|
| Sep-24-2020 16:58:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: LEFT | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

7. Route:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Sep-24-2020 16:58:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Sep-24-2020 16:58:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: THE PROTOCOL SPECIFIED OBS ERVATION PERIOD | Initial Entry |

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Sep-24-2020 16:58:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Oct-27-2020 22:19:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/27/2020 | Initial Entry |

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971064**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Data Origin**

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Oct-27-2020 22:19:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Oct-27-2020 22:19:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|---|
| Oct-27-2020 22:20:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Oct-27-2020 22:19:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Oct-27-2020 22:19:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Oct/27/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Oct-27-2020 22:20:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BL9XGD | Initial Entry |

5.a Sample ID

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Oct-27-2020 22:20:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BL9XGD | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Oct-27-2020 22:20:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sample ID: BL9XFK | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Oct-27-2020 22:20:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BL9XFK | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Oct-27-2020 22:22:25 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sample ID: BPVCM3 | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Oct-27-2020 22:22:25 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BPVCM3 | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Oct-27-2020 22:22:50 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sample ID: BPVC27 | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.d Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Oct-27-2020 22:22:50 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BPVC27 | Initial Entry |

5.e

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Oct-27-2020 22:23:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sample ID: BPVC28 | Initial Entry |

5.e Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Oct-27-2020 22:23:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BPVC28 | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History
Feb/05/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|--|
| Feb-12-2021 08:34:56 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 5: Closed | Response satisfies query |
| Feb-11-2021 13:50:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 5: Answered | not done has been added. |
| Feb-10-2021 18:55:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 4: Closed | Response satisfies query |
| Feb-10-2021 18:54:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 5: Reissued:Opened | The data remains missing on the Microbiology form. If the subject did not have a local test; please add a FORM LEVEL comment of NOT DONE per CCGs. |
| Feb-10-2021 09:53:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 5: Answered | data added |
| Feb-10-2021 09:25:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 4: Answered | data added |
| Feb-08-2021 17:29:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 5: Reissued:Opened | Please provide details on the Microbiology Specimen form. If the subject did not have a local test; please add a FORM LEVEL comment of NOT DONE per CCGs. |
| Feb-08-2021 17:26:05 (UTC-05:00) Eastern | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 4: Reissued:Opened | Please update the data in the SELF |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History
Feb/05/2021**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971064**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39

| | | | | |
|---|-----------------|---------------------------|--------------------|--|
| Time (US & Canada) | | | | SWAB form as it is required to be completed. If sample was not taken specify as 'No' and provide reason as appropriate 'PFE swab taken'. |
| Feb-08-2021 10:03:21 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 5: Answered | data added. |
| Feb-08-2021 09:55:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 4: Answered | this data has been added. |
| Feb-08-2021 07:59:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 5: Opened | DM: Kindly review and complete 'Health Care Utilization, Microbiology Specimen, Illness Details form' at this visit. Thank you. |
| Feb-08-2021 03:41:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 4: Opened | DM: Date of Visit is completed but Self Swab CRF is not initiated. Please review and update the data as appropriate. Thanks |
| Feb-05-2021 13:31:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 3: Deleted | Close Auto Query |
| Feb-05-2021 13:31:25 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 3: Candidate | Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate. |
| Feb-05-2021 13:29:56 (UTC-05:00) Eastern | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History
Feb/05/2021**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971064**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39

| | | | | |
|---|-----------------|---------------------------|----------------------------------|--|
| Time (US & Canada) | | | | |
| Feb-05-2021 13:29:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Deleted | Close Auto Query |
| Feb-05-2021 13:26:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Candidate | Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate. |
| Feb-05-2021 13:26:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate. |
| Feb-05-2021 13:26:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Feb/5/2021 | Initial Entry |

3. COVID-19 Illness Visit:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------|---------------|
| Feb-05-2021 13:26:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: COVID_A | Initial Entry |

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
Feb/05/2021 Audit Trail History**Form Version:** 14-Jan-2021 02:23**Form Status:** Data Complete**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971064**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Date of Assessment:**

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|----------------------------------|---------------|
| Feb-05-2021 13:29:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Feb/5/2021 | Initial Entry |

2. Date of First Symptom Started:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-----------------------------------|--|
| Feb-10-2021 18:53:58 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Feb-10-2021 09:24:52 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | 04-Jan -2021 is correct, |
| Feb-08-2021 17:28:23 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | Please confirm the first symptom started date of 4Jan21 as this is greater than one month prior to the COVID Illness Visit date and clarify delay. |
| Feb-05-2021 13:37:40 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/4/2021 | Transcription Error |
| Feb-05-2021 13:29:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/21/2021 | Initial Entry |

3. Symptoms Ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------------------|-----------------|-----------------------------|
| Mar-09-2021 09:59:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Salim Bouguermouth (b) (4) | Query 1: Closed | Response satisfies query |

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
Feb/05/2021 Audit Trail History**Form Version:** 14-Jan-2021 02:23**Form Status:** Data Complete**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971064**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39

| | | | | |
|---|-----------------|---------------------------------|--|--|
| Mar-09-2021 08:01:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Symptoms are still ongoing. |
| Mar-08-2021 17:29:42 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Salim Bouguermouh (b) (4) | Query 1: Opened | Clin: Please confirm the symptom is still ongoing. |
| Mar-08-2021 15:24:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Transcription Error |
| Mar-08-2021 15:24:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO Date of Last Symptom Resolved: Feb/5/2021 | New Information |
| Feb-05-2021 13:29:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Transcription Error |
| Feb-05-2021 13:29:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Feb-05-2021 13:29:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: FEVER Symptom Present: NO | Initial Entry |

4.a Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-----------------------------|---------------|
| Feb-05-2021 13:29:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: FEVER | Initial Entry |

4.a Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Feb-05-2021 13:29:05 (UTC-05:00) Eastern | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
Feb/05/2021 Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|--------------------|--|--|--|--|
| Time (US & Canada) | | | | |
|--------------------|--|--|--|--|

4.b

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Feb-05-2021 13:29:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present: NO | Initial Entry |

4.b Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Feb-05-2021 13:29:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR INCREASED COUGH | Initial Entry |

4.b Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Feb-05-2021 13:29:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.c

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Feb-05-2021 13:29:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: YES | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
Feb/05/2021 Audit Trail History**Form Version:** 14-Jan-2021 02:23**Form Status:** Data Complete**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971064**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39**4.c Symptoms:**

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Feb-05-2021 13:29:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR INCREASED SHORT NESS OF BREATH | Initial Entry |

4.c Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Feb-05-2021 13:29:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

4.d

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Feb-05-2021 13:29:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: CHILLS Symptom Present: NO | Initial Entry |

4.d Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Feb-05-2021 13:29:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: CHILLS | Initial Entry |

4.d Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Feb-05-2021 13:29:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.e

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Feb-05-2021 13:29:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom NEW OR INCREAS s: ED MUSCLE PAIN | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
Feb/05/2021 Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|--|--|--|---------------------|--|
| | | | Symptom NO Present: | |
|--|--|--|---------------------|--|

4.e Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Feb-05-2021 13:29:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NEW OR INCREASED MUSCL E PAIN | Initial Entry |

4.e Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Feb-05-2021 13:29:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

4.f

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Feb-05-2021 13:29:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Symptoms NEW LOSS OF TA : STE OR SMELL Symptom NO Present: | Initial Entry |

4.f Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Feb-05-2021 13:29:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NEW LOSS OF TASTE OR SME LL | Initial Entry |

4.f Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Feb-05-2021 13:29:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

4.g

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
Feb/05/2021 Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|-----------------|---------------------|--|---------------|
| Feb-05-2021 13:29:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom NEW OR INCREASED SORE THROAT Symptom NO Present: | Initial Entry |
|---|-----------------|---------------------|--|---------------|

4.g Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Feb-05-2021 13:29:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR INCREASED SORE THROAT | Initial Entry |

4.g Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Feb-05-2021 13:29:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.h

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Feb-05-2021 13:29:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: DIARRHEA Symptom Present: NO | Initial Entry |

4.h Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-05-2021 13:29:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: DIARRHEA | Initial Entry |

4.h Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Feb-05-2021 13:29:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.i

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
Feb/05/2021 Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Feb-05-2021 13:29:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: VOMITING Symptom Present: NO | Initial Entry |

4.i Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-05-2021 13:29:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: VOMITING | Initial Entry |

4.i Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Feb-05-2021 13:29:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
Feb/05/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

1. Actual Date of Collection:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-11-2021 13:49:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

2. Specimen Type:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-11-2021 13:49:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

3. Specimen Collection Location:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-11-2021 13:49:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

4. Assay Code and Description:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-11-2021 13:49:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5. Device Type:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-11-2021 13:49:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

6. Trade Name:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-11-2021 13:49:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
Feb/05/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

7. Test Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-11-2021 13:49:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

8. Comments/Findings/Details:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-11-2021 13:49:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

9. Trade Name Other, Specify:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-11-2021 13:49:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History
Feb/05/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------------|
| Feb-10-2021 09:23:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> SITE | Initial Entry |
| Feb-05-2021 13:31:25 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> | Transcription Error |
| Feb-05-2021 13:29:56 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------------|---------------------|
| Feb-10-2021 09:23:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> NASAL_SWAB_SELF | Initial Entry |
| Feb-05-2021 13:31:25 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> | Transcription Error |
| Feb-05-2021 13:29:56 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> NASAL_SWAB_SELF | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--------------------------|---------------------|
| Feb-10-2021 09:23:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |
| Feb-05-2021 13:31:25 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Deleted | Close Auto Query |
| Feb-05-2021 13:31:25 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> | Transcription Error |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Feb/05/2021 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971064**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39

| | | | | |
|---|-----------------|---------------------------|--|---|
| Feb-05-2021 13:31:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Feb-05-2021 13:30:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Feb-05-2021 13:29:56 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Feb-05-2021 13:29:56 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Feb/5/2021 | Initial Entry |

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------------------|---------------|
| Feb-10-2021 09:23:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: done on site. | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---|
| Feb-05-2021 13:31:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BP2RZL | Transcription Error (DELETED) |
| Feb-05-2021 13:30:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BP2RZL | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|----------------------|-----------------|--------------|--------------------|---------------------|
| Feb-05-2021 13:31:11 | ACV0PFEINFP6000 | (b) (4), (b) | Data Entry: | Transcription Error |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/05/2021 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|-----------------|------------------------|------------------------------|--|
| (UTC-05:00) Eastern Time (US & Canada) | | (b) (4), (b) (6) | BP2RZL | (DELETED) |
| Feb-05-2021 13:31:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Feb-05-2021 13:30:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | Barcode is not 7 characters in length. Please review and correct as appropriate. |
| Feb-05-2021 13:30:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BP2RZL | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Feb/05/2021 Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971064**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Data Origin**

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Feb-05-2021 13:31:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Feb-05-2021 13:31:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--|---|
| Feb-05-2021 13:32:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Feb-05-2021 13:31:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Feb-05-2021 13:31:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Feb/5/2021 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Feb-05-2021 13:32:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BP2RZL | Initial Entry |

5.a Sample ID

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/05/2021 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Feb-05-2021 13:32:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BP2RZL | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History
Feb/05/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

1.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Feb-08-2021 10:01:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: SPECIAL IST Occurrence of Visits or Contacts: NO | Initial Entry |

1.a Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|---------------|
| Feb-08-2021 10:01:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: SPECIALIST | Initial Entry |

1.a Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Feb-08-2021 10:01:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

1.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Feb-08-2021 10:01:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1 | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History
Feb/05/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

1.b Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Feb-08-2021 10:01:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EMERGENCY ROOM | Initial Entry |

1.b Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Feb-08-2021 10:01:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES <i>Number of Visits or Contacts:</i> 1 | Initial Entry |

1.c

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Feb-08-2021 10:01:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO | Initial Entry |

1.c Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Feb-08-2021 10:01:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: PRIMARY CARE PHYSICIAN | Initial Entry |

1.c Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Feb-08-2021 10:01:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

1.d

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History
Feb/05/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|-----------------|---------------------|--|---------------|
| Feb-08-2021 10:01:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or NO r Contacts: | Initial Entry |
|---|-----------------|---------------------|--|---------------|

1.d Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Feb-08-2021 10:01:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: URGENT CARE | Initial Entry |

1.d Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Feb-08-2021 10:01:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

1.e

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Feb-08-2021 10:01:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: TELEPHONE C ONSULTATION Occurrence of Vi NO sits or Contacts: | Initial Entry |

1.e Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Feb-08-2021 10:01:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: TELEPHONE CONSULTATION | Initial Entry |

1.e Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Feb-08-2021 10:01:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History
Feb/05/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

1.f

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Feb-08-2021 10:01:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: OTH R Occurrence of Visits or Co ntacts: NO | Initial Entry |

1.f Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------|---------------|
| Feb-08-2021 10:01:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: OTHER | Initial Entry |

1.f Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Feb-08-2021 10:01:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

3. Has the subject been hospitalized due to potential COVID-19 illness?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Feb-08-2021 10:01:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: ILLNESS DETAILS - eCRF Audit Trail History
Feb/05/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

1. Category of Clinical Event:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Feb-08-2021 10:02:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: POTENTIAL COVID-19 ILLNESS | Initial Entry |

2. Was a diagnosis obtained for Potential COVID-19 Illness?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Feb-08-2021 10:02:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

3. Toxicity Grade:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Feb-08-2021 10:02:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 3 | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History
Feb/05/2021

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

1. Lab Panel:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

2. Laboratory Name and Address

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

4. Specimen Type:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Not Done Identifier: Test:: C Reactive Prote in_PX329 Result:: Not Done Not Done:: Not Done Lab Normal Ran Not Done ge: | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History
Feb/05/2021

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|-----------------|---------------------|---|---------------|
| Feb-10-2021 09:46:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Test:: C Reactive Prote in_PX329 Result:: Not Done:: Lab Normal Ran ge: | Initial Entry |
|---|-----------------|---------------------|---|---------------|

5.a Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.a Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Feb-10-2021 09:46:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: C Reactive Protein_PX329 | Initial Entry |

5.a Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.a Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.a LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------------|---------------|
| Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History
Feb/05/2021

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

(US & Canada)

(b) (4), (b) (6)

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Test:: Alanine Aminotransferase_PX30 Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done | Initial Entry |
| Feb-10-2021 09:46:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Test:: Alanine Aminotransferase_PX30 Result:: Not Done:: Lab Normal Range: | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History
Feb/05/2021**Form Version:** 21-Aug-2020 02:49**Form Status:** Data Complete, Frozen**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971064**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39**5.b Sponsor ID:**

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.b Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Feb-10-2021 09:46:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Alanine Aminotransferase_PX30 | Initial Entry |

5.b Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.b Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.b LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Done Test:: Aspartate Aminotransferase_PX28 | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/05/2021 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|-----------------|---------------------|---|---------------|
| | | | Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done | |
| Feb-10-2021 09:46:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Test:: Aspartate Aminotransferase_PX28 Result:: Not Done:: Lab Normal Range: | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History
Feb/05/2021**Form Version:** 21-Aug-2020 02:49**Form Status:** Data Complete, Frozen**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971064**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39**5.c Sponsor ID:**

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.c Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Feb-10-2021 09:46:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aspartate Aminotransferase_PX28 | Initial Entry |

5.c Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.c Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.c LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Not Done Identifier: Test:: Alkaline Phosph atase_PX35 | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/05/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|-----------------|---------------------|---|---------------|
| | | | Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done | |
| Feb-10-2021 09:46:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Test:: Alkaline Phosphatase_PX35 Result:: Not Done:: Lab Normal Range: | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History
Feb/05/2021**Form Version:** 21-Aug-2020 02:49**Form Status:** Data Complete, Frozen**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971064**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39**5.d Sponsor ID:**

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.d Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Feb-10-2021 09:46:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Alkaline Phosphatase_PX35 | Initial Entry |

5.d Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.d Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.d LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.e

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Done Test:: Bilirubin_P X21 | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/05/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|-----------------|---------------------|--|---------------|
| | | | Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done | |
| Feb-10-2021 09:46:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Test:: Bilirubin_P X21 Result:: Not Done:: Lab Normal Range: | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History
Feb/05/2021

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.e Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.e Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Feb-10-2021 09:46:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Bilirubin_PX21 | Initial Entry |

5.e Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.e Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.e LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.f

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Not Done Identifier: Test:: Blood Urea Nitr ogen_PX47 | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/05/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|-----------------|---------------------|--|---------------|
| | | | Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done | |
| Feb-10-2021 09:46:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Test:: Blood Urea Nitrogen_PX47 Result:: Not Done:: Lab Normal Range: | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History
Feb/05/2021

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.f Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.f Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Feb-10-2021 09:46:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Blood Urea Nitrogen_PX47 | Initial Entry |

5.f Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.f Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.f LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.g

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sponsor-Defined Identifier: Test:: Creatinine_P X48 | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/05/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|-----------------|---------------------|---|---------------|
| | | | Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done | |
| Feb-10-2021 09:46:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Test:: Creatinine_P X48 Result:: Not Done:: Lab Normal Range: | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History
Feb/05/2021

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.g Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.g Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------------------|---------------|
| Feb-10-2021 09:46:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Creatinine_PX48 | Initial Entry |

5.g Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.g Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.g LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-10-2021 09:51:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Mar/08/2021

Form: DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|---------------|
| Mar-08-2021 16:49:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Mar/8/2021 | Initial Entry |

3. COVID-19 Illness Visit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Mar-08-2021 16:49:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COVID_A1 | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled
Visit on Mar/08/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1097**Subject No:** 10971064**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Data Origin**

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Mar-08-2021 16:49:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Mar-08-2021 16:49:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--|---|
| Mar-08-2021 16:50:09 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Mar-08-2021 16:49:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Mar-08-2021 16:49:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Mar/8/2021 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Mar-08-2021 16:50:09 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BP2S2S | Initial Entry |

5.a Sample ID

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Mar/08/2021

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Mar-08-2021 16:50:09 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BP2S2S | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Mar-08-2021 16:50:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BP2S2T | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Mar-08-2021 16:50:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BP2S2T | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Mar-08-2021 16:50:44 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BP2S2V | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Mar-08-2021 16:50:44 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BP2S2V | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Mar-08-2021 16:51:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BPN9RV | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Mar/08/2021

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.d Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Mar-08-2021 16:51:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BPN9RV | Initial Entry |

5.e

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Mar-08-2021 16:51:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sample ID: BPN9RW | Initial Entry |

5.e Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Mar-08-2021 16:51:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BPN9RW | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001**Visit:** End of Treatment - Unscheduled**Form Version:** 15-Sep-2020 21:55**Site No:** 1097**Subject No:** 10971064**Generated By:** (b) (4)**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Date of Completion/Discontinuation/Death :**

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|-----------------------------------|---|
| Oct-29-2020 09:22:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Oct-28-2020 15:46:30 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Initial Entry |
| Oct-28-2020 15:46:30 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/27/2020 | Initial Entry |
| Oct-28-2020 13:10:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | CLINQUERY: Please complete the End of Treatment CRF. Per Guidelines, If the Participant receives all vaccinations as per protocol and completes the follow-up visit procedures within the 1-month post vaccination period, report the status as COMPLETED. |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------------|---------------|
| Oct-28-2020 15:46:30 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: VACCINATION | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------------|---------------|
| Oct-28-2020 15:46:30 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|--------|
| Feb-01-2021 08:41:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|--------|
| Feb-05-2021 13:51:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|--------|
| Mar-09-2021 11:25:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Not Complete

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

1. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Feb-01-2021 08:41:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Feb-01-2021 08:41:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 1 | Initial Entry |

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------------|-----------------------|--|
| Mar-09-2021 07:45:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 7: Clos ed | moving query to another item |
| Mar-09-2021 07:44:56 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 7: Ope ned | Clinical - Start date for the persistent A Fib is the same as the start date for the 1st A Fib event; please update this Start date to begin after the 1st A Fib event ends |
| Mar-02-2021 10:08:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Svitlana Tonkovyd (b) (4) | Query 6: Clos ed | Response satisfies query |
| Mar-02-2021 09:56:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 6: Ans wered | INFORMATION UPDATED |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1097**Subject No:** 10971064**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Not Complete**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:39

| | | | | |
|---|---|---------------------------------|--|--|
| Mar-02-2021 09:28:58 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Svitlana Tonkovyd (b) (4) | Query 6: Reissued: Opened | GPD Clin: MH is unlocked now, please kindly add missing MH events. Thanks |
| Mar-01-2021 10:57:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 6: Answered | medical history is frozen, nothing can be added. |
| Mar-01-2021 10:55:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 5: Closed | Discrepancy has been closed. |
| Mar-01-2021 09:48:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Svitlana Tonkovyd (b) (4) | Query 6: Opened | GPD Clin: Per data on SAE report participant also has a MH of gout, overactive bladder, gastroesophageal reflux disease, muscle spasms and bronchospasms. Can you please reconcile and add missing MH events into the MH Inform page? Thanks |
| Mar-01-2021 08:56:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 5: Answered | Transcription Error |
| Mar-01-2021 08:56:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Persistent Atrial Fibrillation | Transcription Error |
| Feb-26-2021 15:57:54 (UTC-05:00) Eastern Time | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 5: Opened | Clarify PERSISTENT ATRIAL FIBRILLATION as |

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1097**Subject No:** 10971064**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Not Complete**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:39

| | | | | |
|---|-----------------|--------------------------------|--|---|
| (US & Canada) | | | | follows...Should the spelling be PERSISTENT ATRIAL FIBRILLATION? If so please edit as such. Otherwise please clarify further. Thank you. |
| Feb-26-2021 12:31:50 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: PERSISTENT ATRIAL FIB RILATION | CHANGED DIAGNOSIS TO MATCH HOSPITAL RECORDS. |
| Feb-25-2021 22:30:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 4: Clos ed | Response satisfies query |
| Feb-17-2021 08:27:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 4: Ans wered | medical history has already been sent in |
| Feb-16-2021 21:34:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 4: Ope ned | Clinical - Please submit to SAE (#2021078077) the recent past medical history of an admission from Jan 04-06, 2020 for the complaint of SOB |
| Feb-10-2021 13:30:42 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Svitlana Tonkoyd (b) (4) | Query 3: Clos ed | closed based on site's response |
| Feb-10-2021 11:02:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Clos ed | Response satisfies query |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Not Complete

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|-----------------|------------------------------|---------------------------|---|
| Feb-09-2021 16:48:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Answered | PCP documentation of 1-19-2021 states, Subject has developed atrial Fibrillation. no other documentation to date. |
| Feb-09-2021 08:25:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Svitlana Tonkovyd (b) (4) | Query 3: Opened | GPD Clin: Please comment on if the subject has any past medical history of Atrial Fibrillation. If yes, please add to medical history. Thank you. |
| Feb-08-2021 17:40:10 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | SAE of SOB entered on AE CRF |
| Feb-05-2021 13:50:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | Changed data per query |
| Feb-05-2021 13:35:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | we are waiting to confirm by medical records the information given to us by the spouse is correct, until then we are unable to confirm. Pt did present with symptoms of shortness of breath and a potential illness visit is being done |
| Feb-05-2021 13:13:17 (UTC-05:00) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued: Opened | Clinical Thank you, please clarify in SAE that Dr. |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1097**Subject No:** 10971064**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Not Complete**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:39

| | | | | |
|---|-----------------|------------------------|--|---|
| Eastern Time (US & Canada) | | | | appt was on 21Jan21. Also please specify per subject/family if the subject had any presenting symptoms |
| Feb-05-2021 13:06:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened | Clinical SAE of Shortness of Breath has been reported (#2021113850) - please enter event on the AE CRF |
| Feb-05-2021 08:22:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Information is based on narrative from the spouse. Spouse stated he went to a doctor appointment on 21Jan2021. Records are pending. |
| Feb-04-2021 19:19:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued: Opened | Clinical - Please clarify if A fib was identified at doctor visit on 21Jan21; was this due to symptoms or was this an asymptomatic discovery? Also update spelling [gibrillation] |
| Feb-02-2021 10:03:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Transcription Error |
| Feb-02-2021 10:03:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: atrial Fibrillation | Transcription Error |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Not Complete

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|-----------------|------------------|---|---|
| Feb-01-2021 18:18:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | Clinical - Please clarify if A fib was identified at doctor visit on 21Jan21; was this due to symptoms or was this an asymptomatic discovery? Also update spelling [gibrillation] |
| Feb-01-2021 08:41:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: atrial gibrillation | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-------------------|---|
| Mar-12-2021 13:05:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 4: Closed | Response satisfies query |
| Mar-12-2021 13:05:09 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | Response satisfies query |
| Mar-12-2021 10:49:49 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Closed | SDB UPDATED |
| Mar-11-2021 08:56:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 4: Answered | There has been 2 updates submitted. Both times were to update what safety requested. The last one submitted was, by request, to change start back to 21Jan21. Thank you |
| Mar-10-2021 22:53:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 4: Opened | Clinical Thank you; however the 09Mar21 SAE followup has updated the start date for Persistent A Fib to 04Jan21. Start date on |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1097**Subject No:** 10971064**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Not Complete**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:39

| | | | | |
|---|-----------------|---------------------------|---|--|
| | | | | AE log is 21Jan21; please review and update where applicable |
| Mar-10-2021 14:10:23 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Reissued:Candidate | pending SDB update |
| Mar-10-2021 08:02:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Answered | SAE update was submitted yesterday. |
| Mar-10-2021 08:00:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | SAE update was submitted yesterday for this subject. |
| Mar-10-2021 07:01:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Opened | SAE RECON: AER#2021078077 ,onset date was recorded as 04Jan2021 in Safety database however, recorded as 21Jan2021 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form. |
| Mar-09-2021 22:57:17 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Reissued:Opened | Clinical - thank you; please submit the a SAE safety update to report the revised start date of 21Jan21 |
| Mar-09-2021 11:12:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Answered | Changed Information |
| Mar-09-2021 11:12:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/21/2021 UNK:UNK | Changed Information |
| Mar-09-2021 09:05:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | requery |

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1097**Subject No:** 10971064**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Not Complete**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:39

| | | | | |
|---|-----------------|---------------------|---|--|
| Mar-09-2021 09:05:32 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened | Clinical - thank you; this is Safety for all your SAEs; please update this SAE so that 2 SAEs with the same name do NOT have the same start date. (note orig term was SOB for 1) |
| Mar-09-2021 08:23:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Date was originally entered separate, however Safety request that they be entered as the same start date. |
| Mar-09-2021 07:45:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | Clinical - Start date for the persistent A Fib is the same as the start date for the 1st A Fib event; please update this Start date to begin after the 1st A Fib event ends |
| Mar-04-2021 10:58:14 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/4/2021 UNK:UNK | Changed Information |
| Feb-01-2021 08:41:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/21/2021 UNK:UNK | Initial Entry |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Not Complete

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|--|
| Mar-09-2021 09:04:08 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Mar-09-2021 08:08:16 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Hospitalization has concluded, however symptoms are still ongoing. |
| Mar-09-2021 07:47:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | Clinical - please review for End date of serious persistent A Fib; has hospitalization concluded for this new ongoing condition (and any other serious criterion) |
| Feb-01-2021 08:41:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Feb-01-2021 08:41:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 3 | Initial Entry |

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------|-----------------------------|
| Mar-10-2021 22:47:20 (UTC-05:00) Eastern | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 4: Closed | Response satisfies query |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Not Complete

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| Time (US & Canada) | | | | |
|---|-----------------|---------------------|--------------------------|--|
| Mar-09-2021 14:03:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 4: Answered | Subject is no longer hospitalized, however he is not recovered. |
| Mar-09-2021 09:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 4: Opened | Clinical - If serious [SAE] status for A Fib continues after hospital discharge, please update with a non-Hospitalization serious criterion |
| Feb-25-2021 22:31:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Closed | Query closed; will follow for requested COVID test information. |
| Feb-17-2021 10:44:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Answered | will update and send SAE follow up form today |
| Feb-16-2021 21:30:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Reissued:Opened | Clinical – Thank you. If awaiting additional records, please submit 'Awaiting Med Records to Determine if COVID testing was Performed' as a SAE safety followup. |
| Feb-10-2021 15:20:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Answered | Issue is that we don't know. |
| Feb-10-2021 11:03:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Opened | Clinical – Thank you. If NO hospital COVID test was performed is known, please submit this information on a follow-up SAE form (#2021078077), as pertinent information for this trial. |
| Feb-04-2021 19:22:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | Clinical – Thank you. If NO hospital COVID test was |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Not Complete

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|--|-----------------|------------------------|--|---|
| | | | | performed is known, please submit this information on a follow-up SAE form, as pertinent information for this trial. |
| Feb-03-2021 13:58:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | site has no documentation of any covid testing. |
| Feb-02-2021 13:16:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Feb-02-2021 10:03:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | For AE atrial Fibrillation: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank. |
| Feb-01-2021 18:16:23 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened | Clinical COVID test status (yes/no) during Hosp was not reported in the SAE. Please submit a follow-up SAE form [#2021078077] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results. |
| Feb-01-2021 08:41:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | For AE atrial gibrillation: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank. |
| Feb-01-2021 08:41:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1097**Subject No:** 10971064**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Not Complete**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:39

| | | | | |
|--|--|--|---|--|
| | | | NO | |
| | | | Did this serious event result in death? | |
| | | | NO | |
| | | | Did this serious event require or prolong hospitalization? | |
| | | | YES | |
| | | | Did this serious event result in persistent or significant disability/incapacity? | |
| | | | NO | |
| | | | Is this serious event life threatening? | |
| | | | NO | |
| | | | Other medically important serious event | |
| | | | NO | |

8. Is this adverse event the result of a study Medication Error?*If Yes, record the type of medication error on the Medication Error Log.*

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Feb-01-2021 08:41:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

9. Is this event related to study treatment:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Feb-01-2021 08:41:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER | Initial Entry |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Not Complete

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|--|--|--|---------------------------|--|
| | | | | |
| | | | <i>If Other, specify:</i> | |
| | | | unknown | |

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Feb-01-2021 08:41:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Feb-01-2021 08:41:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Feb-01-2021 08:41:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

13. What was the outcome of this adverse event?:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--|--------------------------|
| Mar-03-2021 15:46:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Closed | Response satisfies query |
| Mar-03-2021 09:05:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 3: Answered | Transcription Error |
| Mar-03-2021 09:05:28 (UTC-05:00) Eastern Time (US | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RECOVERING/RE SOLVING | Transcription Error |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Not Complete

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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|---|-----------------|---------------------------|--|---|
| & Canada) | | | | |
| Mar-03-2021 05:36:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Opened | SAE RECON:AER#2021078077,outcome was reported as Recovering/Resolvingto Safety DB however, recorded as NOT RECOVERED/NOT RESOLVED on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form. |
| Feb-03-2021 12:08:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Closed | Close Auto Query |
| Feb-03-2021 12:08:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT RECOVERED /NOT RESOLVED | New Information |
| Feb-02-2021 10:03:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Opened | For AE atrial Fibrillation: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes". |
| Feb-01-2021 14:37:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Feb-01-2021 08:42:51 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | at this time we do not know. Medical records are pending |
| Feb-01-2021 08:41:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | For AE atrial gibrillation: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes". |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Not Complete

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|-----------------|---------------------|-------------------------------|---------------|
| Feb-01-2021 08:41:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> UNKNOWN | Initial Entry |
|---|-----------------|---------------------|-------------------------------|---------------|

14. Did the adverse event cause the subject to be discontinued from the study?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Feb-01-2021 08:41:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

15. Serious Adverse Event Number: For Pfizer Use Only

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|---------------|
| Feb-02-2021 13:16:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> 2021078077 | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

1. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Feb-05-2021 13:51:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Feb-05-2021 13:51:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 2 | Initial Entry |

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------|--|
| Mar-05-2021 22:01:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 6: Closed | Query closed; will follow for requested event term update |
| Mar-05-2021 22:00:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 5: Closed | Query closed; will follow for requested SAE event term update. |
| Mar-04-2021 10:42:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 6: Answered | resent on 3/3/2021 |
| Mar-03-2021 09:06:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 5: Answered | new SAE paper work has been submitted |
| Mar-03-2021 05:35:09 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 4: Closed | Response satisfies query |
| Mar-03-2021 00:50:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 6: Opened | Clinical - please submit the relevant prior med history to SAE #2021113850 |
| Mar-03-2021 00:38:18 (UTC-05:00) Eastern | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 5: Opened | CLINICAL - event term is New Onset |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|-----------------|------------------|--|---|
| Time (US & Canada) | | | | Atrial Fibrillation; however, the SAE report event term is Atrial Fibrillation. Please review, harmonize reporting, and update where applicable |
| Mar-03-2021 00:37:08 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Closed | Response satisfies query |
| Mar-02-2021 08:40:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 4: Answered | TERM WAS UPDATED TO NEW ONSET AFIB AND SAFETY UPDATE WAS FAXED ON 26 FEB 2021 |
| Mar-01-2021 22:46:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 4: Opened | SAE RECON: AER#2021113850, the term was reported as 'SHORTNESS OF BREATH' in Safety database while recorded as 'NEW ONSET ATRIAL FIB' in AE CRF. Please confirm correct term. If safety update is required, please submit a follow-up form. |
| Feb-26-2021 12:28:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW ONSET ATRIAL FIB | CHANGED DIAGNOSIS AFTER RECEIVING HOSPITAL RECORDS. |
| Feb-26-2021 08:08:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Answered | sending in updated information today |
| Feb-25-2021 22:34:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Reissued: Opened | Clinical Followup - most recent SAE update (08Feb21) does not include information for the event; please update |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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|--|-----------------|------------------------|---|--|
| | | | | with testing, treatment if available |
| Feb-17-2021 08:30:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Answered | sending in an update |
| Feb-16-2021 21:40:32 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Opened | Clinical - SAE states that 'relevant tests are unknown' for the event of SOB; please update the SAE report with some info on treatment, and testing if available |
| Feb-16-2021 21:30:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | Response satisfies query |
| Feb-10-2021 15:23:09 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Answered | ok |
| Feb-10-2021 15:23:09 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: shortness of breath | ok |
| Feb-10-2021 11:06:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | SAE Recon will ensure data re appropriately updated. |
| Feb-10-2021 10:57:17 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened | Clinical SAE (#2021113850) event term is 'Shortness of Breath'; however, AE CRF has 'SOB was the A/e date is 4-Jan2021'. Please update AE CRF removing extraneous date information from SAE event term |
| Feb-10-2021 09:49:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | response to query |
| Feb-10-2021 09:49:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: shortness of breath was the A/e date is 4-Jan-2021 | response to query |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1097**Subject No:** 10971064**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:39

| | | | | |
|---|-----------------|---------------------|---|---|
| Feb-08-2021 17:01:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Opened | CLINREQUERY: Per the Signs and Symptoms CRF, SHORTNESS OF BREATH is also entered with the same START Date (4-Jan-21). Therefore, please confirm this AE Record should not also be entered on the AE CRF and update the data. Otherwise, clarify. |
| Feb-08-2021 16:38:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | No, medical records do not document anything about COVID-19. |
| Feb-08-2021 14:48:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | CLINQUERY: Please Specify if the PI thought this SHORTNESS OF BREATH could have been related to COVID-19. Please provide a response as there was no Covid Illness Visit done. |
| Feb-05-2021 13:51:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: shortness of breath | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Feb-05-2021 13:51:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/4/2021 UNK:UNK | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------|-----------------------------|
| Feb-08-2021 13:27:45 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1097**Subject No:** 10971064**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:39

| | | | | |
|---|-----------------|---------------------------|--|--|
| Feb-08-2021 09:52:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | New Information |
| Feb-08-2021 09:52:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date Time: Jan/6/2021 UNK:UNK | New Information |
| Feb-08-2021 09:44:50 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | DM Q: Outcome is Recovered/Resolved however END Date and Time is missing. Please review and update as appropriate |
| Feb-05-2021 13:51:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Feb-05-2021 13:51:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 3 | Initial Entry |

7. Is the adverse event serious?**If Yes, NOTIFY PFIZER IMMEDIATELY.**

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|--|
| Feb-25-2021 22:32:17 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | Query closed; will follow for requested COVID test information. |
| Feb-17-2021 08:30:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | sending in an update |
| Feb-16-2021 21:31:20 (UTC-05:00) Eastern | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Reissued:Opened | Clinical – Thank you. If awaiting |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|-----------------|------------------------|--------------------------|---|
| Time (US & Canada) | | | | additional records, please submit 'Awaiting Med Records to Determine if COVID testing was Performed' as a SAE safety followup. |
| Feb-10-2021 15:24:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | not known. |
| Feb-10-2021 10:58:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Reissued:Opened | Clinical – Thank you. If NO hospital COVID test was performed is known, please submit this information on a follow-up SAE form, as pertinent information for this trial. |
| Feb-10-2021 09:42:44 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | No record of COVID testing. |
| Feb-08-2021 17:52:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened | Clinical COVID test status (yes/no) during Hosp for SOB was not reported in the SAE. Please submit a follow-up SAE form [#2021113850] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results. |
| Feb-08-2021 09:44:08 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Feb-05-2021 13:51:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | For AE shortness of breath: Response to "Is the adverse event |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|-----------------|---------------------|---|---|
| | | | | serious?" is 'Yes' but "Serious Adverse Event Number" is blank. |
| Feb-05-2021 13:51:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <p>Data Entry: YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p> | Initial Entry |

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|---------------|
| Feb-05-2021 13:51:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <p>Data Entry: NO</p> | Initial Entry |

9. Is this event related to study treatment:

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Feb-05-2021 13:51:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT RELATED If Not Related to study treatment (s), this event is due to: OTHER <i>If Other, specify:</i> unknown | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Feb-05-2021 13:51:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Feb-05-2021 13:51:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Feb-05-2021 13:51:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

13. What was the outcome of this adverse event?:

| Date | Location | User | Value | Reason |
|---|---|-------------------|---|---|
| Feb-08-2021 13:27:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Feb-08-2021 09:54:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | has been answered. |
| Feb-05-2021 22:03:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY (b) (4) | Query 1: Opened | DMW7171323;Response to "What was the outcome of this adverse event?" is 'Recovered/Resolved' or 'Recovered/Resolved with Sequelae' but End Date/Time is missing. Please review and update as appropriate. |
| Feb-05-2021 13:51:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry : REC OVE RED/ RESO LVED | Initial Entry |

14. Did the adverse event cause the subject to be discontinued from the study?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Feb-05-2021 13:51:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

15. Serious Adverse Event Number: For Pfizer Use Only

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|---------------|
| Feb-08-2021 09:44:08 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> 2021113850 | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

1. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Mar-09-2021 11:25:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Mar-09-2021 11:25:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 3 | Initial Entry |

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------------|--|--|
| Mar-12-2021 13:32:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Svitlana Tonkovyd (b) (4) | Query 1: Closed | closed per site's response |
| Mar-12-2021 07:51:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | a diagnosis of congestive heart failure is due to fluid retention but the reason for the fluid retention is unknown. |
| Mar-11-2021 17:19:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Svitlana Tonkovyd (b) (4) | Query 1: Opened | GPD Clin: Pls provide details on how diagnosis was made, what was the reason for fluid retention? Thanks |
| Mar-09-2021 11:25:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: congestive heart failure | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|-----------------|---------------------|---|---------------|
| Mar-09-2021 11:25:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Dec/22/2020 UNK:UNK | Initial Entry |
|---|-----------------|---------------------|---|---------------|

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Mar-09-2021 11:25:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> YES | Initial Entry |

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Mar-09-2021 11:25:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> 2 | Initial Entry |

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Mar-09-2021 11:25:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Mar-09-2021 11:25:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

9. Is this event related to study treatment:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---------------------|-----------------------------|
| Mar-12-2021 15:50:54 (UTC-05:00) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Cl osed | Response satisfies query |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001
Visit: Logs - Unscheduled
Form Version: 22-Apr-2020 21:02
Site No: 1097
Subject No: 10971064
Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Status: Data Complete
Site Name: (1097) Main Street Physician's Care - Waterway
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|---|-------------------------|---|--|
| Eastern Time (US & Canada) | | | | |
| Mar-12-2021 09:25:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | congestive heart failure is caused by fluid retention, this is a new finding for subject. no other condition or pre existing event for this |
| Mar-12-2021 08:16:51 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFE SDQ PROD (b) (4) | Query 1: Opened | Please review "If not related to study treatment other" field, the following text was indicated in the comment field [fluid retention]. Kindly confirm this condition is related to any pre existing event, if so please review and update the Medical History, else clarify. (b) (4) |
| Mar-09-2021 11:25:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry ↓ NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify</i> | Initial Entry |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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| | | | on | |

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Mar-09-2021 11:25:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Mar-09-2021 11:25:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Mar-09-2021 11:25:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

13. What was the outcome of this adverse event?:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Mar-09-2021 11:25:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RECOVERING/RESOLVING | Initial Entry |

14. Did the adverse event cause the subject to be discontinued from the study?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Mar-09-2021 11:25:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Jan-20-2021 16:48:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/14/2021 | Initial Entry |

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail
History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

1. Select appropriate response - Is participant willing to return for Vaccination 3?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---|
| Feb-25-2021 09:38:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Participant is willing to return fo r Vaccination 3 Participant is: eligible and NOT confirmed t o have received only placebo at Vaccination 1/2 | update |
| Feb-02-2021 11:16:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Feb-01-2021 16:12:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | information uploaded in florence today |
| Feb-01-2021 11:49:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | Monitor is unable to verify if visit occurred. There is no supporting documentation via Florence. Please confirm if visit occurred, if so, please upload supporting documentation to be verified. Thanks |
| Jan-20-2021 16:48:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Participant is NOT willing to ret urn for Vaccination 3 OR otherw ise not eligible | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

1. Date Treatment Unblinded :

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Jan-20-2021 16:47:50 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/14/2021 | Initial Entry |

2. Primary Reason for Unblinding:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---|
| Feb-25-2021 14:28:40 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1 : Close d | data updated |
| Feb-25-2021 09:38:44 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1 : Answ ered | updated |
| Feb-25-2021 05:47:17 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1 : Reissu ed:Ope ned | DM: Form unfrozen, kindly review and update. |
| Feb-24-2021 04:06:08 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1 : Reissu ed:Can didate | DM: Form unfrozen, kindly review and update. |
| Feb-23-2021 12:47:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1 : Answ ered | please unfreeze the page that we need to update to fix, FURTHER VACCINATION CONFIRMATION |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|---|----------------------|---|---|
| Feb-22-2021 18:54:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1 : Reissued: Opened | DM RQ: Per CCG, if the subject is eligible prior to determining whether or not placebo was given at V1/V2, consider entering Participant is willing to return for Vaccination 3 and eligible and NOT confirmed to have received only placebo at Vaccination 1/2 |
| Feb-22-2021 09:25:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1 : Answered | pt received real IP at the beginning of study and does not qualify for additional vaccinations |
| Feb-22-2021 08:23:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY (b) (4) | Query 1 : Opened | DMW7349439;Primary Reason for Unblinding is "ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION", but "Participant is willing to return for Vaccination 3" is not selected in the Further Vaccination Confirmation CRF. Please review and update as appropriate. |
| Jan-20-2021 16:47:50 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

1. Subject Status

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Oct-28-2020 15:46:30 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: FOLLOW-UP | Initial Entry |
| Sep-02-2020 13:17:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ENROLLED/RANDOMIZED | Initial Entry |
| Sep-02-2020 09:06:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SCREENED | Initial Entry |

2. Subject Status Date

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------|--|
| Feb-11-2021 14:07:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | Log updated |
| Feb-05-2021 13:52:10 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | Changed data per query |
| Feb-05-2021 12:41:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened | SAE RECON:AER#2021113850 SHORTNESS OF BREATH(onset date:04- JAN-2021)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form. |
| Feb-01-2021 18:14:44 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Feb-01-2021 08:43:08 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | added to AE Log |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971064

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|-----------------|-------------------------|-----------------------------------|---|
| Jan-29-2021 11:21:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | Clinical - Please enter the SAE (#2021078077) of 'Atrial Fibrillation' on the AE CRF |
| Oct-28-2020 15:46:30 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Oct/27/2020 | Initial Entry |
| Sep-02-2020 13:17:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Aug/31/2020 | Initial Entry |
| Sep-02-2020 09:06:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Aug/31/2020 | Initial Entry |

090177e196ae3ead\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1097

Subject No: 10971064

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

1. Casebook Signature

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Oct-21-2020 22:58:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Click Here to Enable | Initial Entry |