

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[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: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Informed Consent

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: DEMOGRAPHY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Demography

| | | |
|----|---------------------------------|--|
| 1. | Subject ID | [10191146] |
| 2. | Birth Date: | (b) (6) /1952 |
| 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: | |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Form Comments

Inclusion Criteria Not Met

| | | |
|----|--|----------------|
| 1. | Description of Inclusion Criterion Not Met | Not Applicable |
|----|--|----------------|

Exclusion Criteria Met

| | | |
|----|--|----------------|
| 2. | Description of Exclusion Criterion Met | Not Applicable |
|----|--|----------------|

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition - Screening

| | | |
|----|--|------------|
| 1. | Date of Completion/Discontinuation/Death | Sep/1/2020 |
| 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: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Medical History Details

| | | |
|-----|--|----------------|
| 1.a | Line/MH Number: | [1] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Myopia] |
| | Start Date: | UNK/UNK/1960 |
| | Ongoing: | YES |
| 1.b | Line/MH Number: | [2] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [asthma] |
| | Start Date: | UNK/UNK/1985 |
| | Ongoing: | YES |
| 1.c | Line/MH Number: | [3] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [sleep apnea] |
| | Start Date: | Nov/UNK/2019 |
| | Ongoing: | YES |
| 1.d | Line/MH Number: | [4] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Hypertension] |
| | Start Date: | UNK/UNK/2016 |
| | Ongoing: | YES |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

| | | |
|-----|--|-------------------------|
| 1.e | Line/MH Number: | [5] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Hypercholesterolemia] |
| | Start Date: | UNK/UNK/2002 |
| | Ongoing: | YES |
| 1.f | Line/MH Number: | [6] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Atrial Fibrillation] |
| | Start Date: | Oct/30/2019 |
| | Ongoing: | YES |
| 1.g | Line/MH Number: | [7] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Gastric Reflux] |
| | Start Date: | UNK/UNK/2000 |
| | Ongoing: | YES |
| 1.h | Line/MH Number: | [8] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Hemorrhoids] |
| | Start Date: | UNK/UNK/1990 |
| | Ongoing: | YES |
| 1.i | Line/MH Number: | [9] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Osteoarthritis- knees] |
| | Start Date: | UNK/UNK/2010 |
| | Ongoing: | YES |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

| | | |
|-----|--|-----------------------|
| 1.j | Line/MH Number: | [10] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Leg Cramps] |
| | Start Date: | UNK/UNK/1972 |
| | Ongoing: | YES |
| 1.k | Line/MH Number: | [11] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Recurrent Back pain] |
| | Start Date: | UNK/UNK/2010 |
| | Ongoing: | YES |
| 1.l | Line/MH Number: | [12] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Allergic Rhinitis] |
| | Start Date: | UNK/UNK/1986 |
| | Ongoing: | YES |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vital Signs

| | | |
|----|------------------|------------|
| 1. | Date: | Sep/1/2020 |
| 2. | Weight: | [255.6] |
| 3. | Unit: | LB |
| 4. | Height: | [67.25] |
| 5. | Unit: | in |
| 6. | Body Mass Index: | [39.7] |

Vital Signs Details

| | | |
|-----|-----------------------|--------|
| 7.a | Record Identifier: | 1 |
| | Temperature: | [98.7] |
| | Unit: | F |
| | Temperature Location: | EAR |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition

| | | |
|----|-----------------------|------------|
| 1. | Randomization Date : | Sep/1/2020 |
| 2. | Randomization Number: | [248851] |
| 3. | Randomization Group: | [] |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|--|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Sep/1/2020 |
| 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 | [BP98C0] |
| 5.b | Sample ID | [BP98C1] |
| 5.c | Sample ID | [BP98C2] |
| 5.d | Sample ID | [BPRMD3] |
| 5.e | Sample ID | [BPRMD4] |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|--|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Sep/1/2020 |
| 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 | [BM864N] |
|-----|-----------|----------|

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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/1/2020 14:40 |
| 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 |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Sep/22/2020 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vital Signs

| | | |
|----|-------|-------------|
| 1. | Date: | Sep/22/2020 |
|----|-------|-------------|

Vital Signs Details

| | | |
|-----|-----------------------|--------|
| 2.a | Record Identifier: | 1 |
| | Temperature: | [97.8] |
| | Unit: | F |
| | Temperature Location: | EAR |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Sep/22/2020 |
| 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 | [BP98MB] |
|-----|-----------|----------|

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[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/22/2020 07:56 |
| 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 |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[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: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[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 | [BR85SM] |
| 5.b | Sample ID | [BRTM3T] |
| 5.c | Sample ID | [BRTM3V] |
| 5.d | Sample ID | [BRTM3W] |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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 | [] |
|----|-----------|-----|

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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 | [] |
|----|-----------|-----|

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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 | [] |
|----|-----------|-----|

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

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

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Signs and Symptoms

| | | |
|----|--------------------------------|----|
| 1. | Date of Assessment: | // |
| 2. | Date of First Symptom Started: | // |
| 3. | Symptoms Ongoing? | |

Symptoms

| | | |
|----|----------------------|--|
| 4. | Symptoms: | |
| | Was symptom present? | |

Symptoms - Other

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

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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 | [] |
|----|-----------|-----|

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Health Care Utilization

| | | |
|----|---------------------------------------|--|
| 1. | Physician or Healthcare Professional: | |
| | Occurrence of Visits or Contacts: | |

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? | |
|----|--|--|

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52 **Form Status:** Not Started

Site No: 1019 **Site Name:** (1019) Diagnostics Research Group

Subject No: 10191146 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 04:44

Illness Details

| | | |
|----|--|--|
| 1. | Category of Clinical Event: | |
| 2. | Was a diagnosis obtained for Potential COVID-19 Illness? | |
| 3. | Toxicity Grade: | |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

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

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Unplanned Assessments

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

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: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[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: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Data Complete, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition - Follow-Up

| | | |
|----|--|-------------|
| 1. | Date of Completion/Discontinuation/Death : | Dec/17/2020 |
| 2. | Phase of Disposition: | FOLLOW-UP |
| 3. | Status: | DEATH |
| 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: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

| # | Category | AE Identifier | Adverse Event | Start Date | Is the Adverse Event Still Ongoing | Form Instance |
|----|---------------|---------------|---------------------------|---------------------|---|---------------------------------|
| 1. | ADVERSE EVENT | 1 | Biliary Cancer Metastatic | Oct/27/2020 UNK:UNK | NO End Date Time: Dec/17/2020 UNK:UNK | Repeating Pages |
| 2. | ADVERSE EVENT | 2 | Metastases to Liver | Oct/27/2020 UNK:UNK | NO End Date Time: Dec/17/2020 UNK:UNK | Repeating Pages |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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[Form Audit Trail](#)

Adverse Event Report

| | | |
|----|---|--|
| 1. | Category: | ADVERSE EVENT |
| 2. | AE ID: | [1] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [Biliary Cancer Metastatic] |
| 4. | Start Date Time: | Oct/27/2020 UNK:UNK |
| 5. | Is the adverse event still ongoing? | NO End Date Time: Dec/17/2020 UNK:UNK |
| 6. | Toxicity Grade: | 4 |
| 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? YES Did this serious event require or prolong hospitalization? NO Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event YES |
| 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 |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

| | | |
|-----|--|--|
| 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? | NO |
| 12. | Was a Non-Drug Treatment given? | NO |
| 13. | What was the outcome of this adverse event?: | FATAL |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | YES |
| 15. | Serious Adverse Event Number: For Pfizer Use Only | [2020420011] |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Adverse Event Report

| | | |
|----|---|--|
| 1. | Category: | ADVERSE EVENT |
| 2. | AE ID: | [2] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [Metastases to Liver] |
| 4. | Start Date Time: | Oct/27/2020 UNK:UNK |
| 5. | Is the adverse event still ongoing? | NO End Date Time: Dec/17/2020 UNK:UNK |
| 6. | Toxicity Grade: | 4 |
| 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? YES Did this serious event require or prolong hospitalization? NO Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event YES |
| 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 |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

| | | |
|-----|--|--|
| 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: [metastatic biliary cancer] |
| 10. | Latest Action Taken with Study Treatment: | NOT APPLICABLE |
| 11. | Was a Concomitant Medication given? | NO |
| 12. | Was a Non-Drug Treatment given? | NO |
| 13. | What was the outcome of this adverse event?: | FATAL |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | YES |
| 15. | Serious Adverse Event Number: For Pfizer Use Only | [2020420011] |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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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 | [] |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

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: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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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: | // |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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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? | |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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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: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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| | | |
|----|----------------------|----|
| 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: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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? | |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (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: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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: Not Started

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

| | | |
|----|-----------------|----|
| 1. | Date of Visit | // |
| 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: Not Started

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Further Vaccination Confirmation

| | | |
|----|---|--|
| 1. | Select appropriate response - Is participant willing to return for Vaccination 3? | |
|----|---|--|

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Not Started

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Treatment Unblinded

| | | |
|----|--------------------------------|----|
| 1. | Date Treatment Unblinded : | // |
| 2. | Primary Reason for Unblinding: | |

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Withdrawal Of Consent

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

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Data Complete, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Death Details

| | | |
|----|---|------------|
| 1. | Date of Collection / Notification of Death: | Feb/5/2021 |
|----|---|------------|

Cause of Death

| | | |
|-----|------------------------|-----------------------------|
| 2.a | Cause of Death Status: | PRIMARY CAUSE OF DEATH |
| | Cause of Death: | [METASTASES TO LIVER] |
| 2.b | Cause of Death Status: | SECONDARY CAUSE OF DEATH |
| | Cause of Death: | [BILIARY CANCER METASTATIC] |

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Subject Status

| | | |
|----|---------------------|--------------|
| 1. | Subject Status | DISCONTINUED |
| 2. | Subject Status Date | Dec/17/2020 |

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[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, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Audit Trail](#)

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

- CRF_Sign
- CRF_Sign_1

| Name | Signature Meaning | Date | Type | Action |
|------|-------------------|------|------|--------|
|------|-------------------|------|------|--------|

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| Form | Sep-01-2020 15:52:47 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

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

- CRF_Sign
- CRF_Sign_1

| Name | Signature Meaning | Date | Type | Action |
|---------|-------------------|---|------|-----------------------------------|
| (b) (6) | N/A | Feb-05-2021 09:04:44 (UTC-06:00) Central Time (US & Canada) | | Edit - All signatures invalidated |

Affidavit:

N/A

| | | | | |
|---------|----------|---|------|--------|
| (b) (6) | Approved | Dec-03-2020 13:59:39 (UTC-06:00) Central Time (US & Canada) | BOOK | Signed |
|---------|----------|---|------|--------|

Affidavit:

By my dated signature below, I, (b) (6), 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 | Nov-19-2020 09:28:58 (UTC-06:00) Central Time (US & Canada) | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|---------|----------|---|------|--------|
| (b) (6) | Approved | Nov-16-2020 13:53:12 (UTC-06:00) Central Time (US & Canada) | BOOK | Signed |
|---------|----------|---|------|--------|

Affidavit:

By my dated signature below, I, (b) (6), 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.

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Select appropriate response - Protocol version

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-01-2020 15:51:58 (UTC-06:00) Central 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-01-2020 15:51:58 (UTC-06:00) Central 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: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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I. Consent Was:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-01-2020 15:52:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: OBTAINED Date Written Consent Obtained Sep/1/2020 | Initial Entry |

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Subject ID

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------|-----------------------------------|
| Sep-01-2020 15:51:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 10191146 | Item copied from previous form |

2. Birth Date:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---|
| Oct-30-2020 05:33:47 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Oct-29-2020 09:19:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | submitted a follow up SAE with correction. Thank you |
| Oct-29-2020 03:49:21 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | SAE RECON:AER#2020420011, the date of birth was reported as (b) (6) 1950 in Safety database but was recorded as (b) (6) 1952 in AE CRF. Please confirm if date of birth was reported. If safety update is required, please submit a follow-up form. |
| Sep-01-2020 15:51:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: (b) (6) /1952 | Enrollment Entry |

3. Sex:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------|---------------|
| Sep-01-2020 15:52:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: MALE | Initial Entry |

4. Ethnicity:

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-01-2020 15:52:32 (UTC-06:00) Central 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-01-2020 15:52:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: WHITE | Initial Entry |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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I. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|---|
| Oct-06-2020 01:09:34 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Per site confirmation |
| Oct-05-2020 09:11:48 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Subject symptoms were not COVID regulated |
| Sep-29-2020 08:52:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | As per Illness ediary records, subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 09SEP2020. But there is no COVID Illness visit reported in the database. Please clarify. |
| Sep-01-2020 15:52:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/1/2020 | Initial Entry |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Completion/Discontinuation/Death

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|---------------|
| Sep-01-2020 15:53:07 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/1/2020 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Sep-01-2020 15:53:07 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SCREENING | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------------|---------------|
| Sep-01-2020 15:53:07 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1.a

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Sep-01-2020 15:53:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number 1 : Medical History T Myopia erm: Start Date: UNK/UNK/1 960 Ongoing: YES | Initial Entry |

1.a Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-01-2020 15:53:32 (UTC-06:00) Central 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 |
|---|-----------------|-------------------------------|-------------------|---|
| Nov-07-2020 06:41:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Charu Sabharwal (b) (4) | Query 1: Closed | Issued on INCORRECT subject. Query closed. |
| Nov-06-2020 13:44:22 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Please verify if correct site. Pt does not have SAE of heroin overdose. |
| Nov-06-2020 01:23:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | Clinical - SAE subject with heroin overdose; please clarify if subject is now understood to be a chronic drug user, with past medical history of drug abuse w/ or |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

| | | | | |
|--|-----------------|---------------------|------------------------------|--|
| | | | | w/o overdoses or other complications |
| Nov-05-2020 15:14:24 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Candidate | Clinical - SAE subject with heroin overdose; please clarify if subject is now understood to be a chronic drug user, with past medical history of drug abuse w/ or w/o overdoses or other complications |
| Sep-01-2020 15:53:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Myopia | Initial Entry |

I.a Start Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------------|---------------|
| Sep-01-2020 15:53:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/1960 | Initial Entry |

I.a Ongoing:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------|---------------|
| Sep-01-2020 15:53:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

I.b

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Sep-01-2020 15:53:44 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number 2 : Medical History T asthma erm: Start Date: UNK/UNK/1 985 Ongoing: YES | Initial Entry |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.b Line/MH Number:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------|---------------|
| Sep-01-2020 15:53:44 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 2 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Sep-01-2020 15:53:44 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: asthma | Initial Entry |

1.b Start Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------------|---------------|
| Sep-01-2020 15:53:44 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/1985 | Initial Entry |

1.b Ongoing:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------|---------------|
| Sep-01-2020 15:53:44 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

1.c

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Sep-01-2020 15:53:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 3 Medical History Term: sleep apnea Start Date: Nov/UNK/2019 Ongoing: YES | Initial Entry |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

I.c Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-01-2020 15:53:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 3 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-01-2020 15:53:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: sleep apnea | Initial Entry |

I.c Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Sep-01-2020 15:53:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Nov/UNK/2019 | Initial Entry |

I.c Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Sep-01-2020 15:53:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

I.d

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Sep-01-2020 15:54:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number 4 : Medical History T Hypertension erm: Start Date: UNK/UNK/2 016 Ongoing: YES | Initial Entry |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.d Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-01-2020 15:54:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 4 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Sep-01-2020 15:54:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Hypertension | Initial Entry |

1.d Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Sep-01-2020 15:54:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> UNK/UNK/2016 | Initial Entry |

1.d Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Sep-01-2020 15:54:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> YES | Initial Entry |

1.e

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Sep-01-2020 15:54:24 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Line/MH Numb 5 er: Medical History Hypercholesterolemia Term: Start Date: UNK/UNK/2002 Ongoing: YES | Initial Entry |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

I.e Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-01-2020 15:54:24 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 5 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-01-2020 15:54:24 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Hypercholesterolemia | Initial Entry |

I.e Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Sep-01-2020 15:54:24 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> UNK/UNK/2002 | Initial Entry |

I.e Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Sep-01-2020 15:54:24 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> YES | Initial Entry |

I.f

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Sep-01-2020 15:54:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Line/MH Number 6 : Medical History T Atrial Fibrilla erm: tion Start Date: Oct/30/2019 Ongoing: YES | Initial Entry |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.f Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-01-2020 15:54:52 (UTC-06:00) Central 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-01-2020 15:54:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Atrial Fibrillation | Initial Entry |

1.f Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-01-2020 15:54:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/30/2019 | Initial Entry |

1.f Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Sep-01-2020 15:54:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

1.g

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Sep-01-2020 15:55:08 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number 7 : Medical History Term: Gastric Reflu x Start Date: UNK/UNK/2 000 Ongoing: YES | Initial Entry |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

I.g Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-01-2020 15:55:08 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 7 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Sep-01-2020 15:55:08 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Gastric Reflux | Initial Entry |

I.g Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Sep-01-2020 15:55:08 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> UNK/UNK/2000 | Initial Entry |

I.g Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Sep-01-2020 15:55:08 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> YES | Initial Entry |

I.h

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Sep-01-2020 15:55:24 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Line/MH Number 8 : Medical History T Hemorrhoids erm: Start Date: UNK/UNK/1 990 Ongoing: YES | Initial Entry |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.h Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-01-2020 15:55:24 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 8 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-01-2020 15:55:24 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Hemorrhoids | Initial Entry |

1.h Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Sep-01-2020 15:55:24 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> UNK/UNK/1990 | Initial Entry |

1.h Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Sep-01-2020 15:55:24 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> YES | Initial Entry |

1.i

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Sep-01-2020 15:55:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Line/MH Numbe 9 r: Medical History Osteoarthritis- Term: knees Start Date: UNK/UNK/20 10 Ongoing: YES | Initial Entry |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.i Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-01-2020 15:55:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 9 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-01-2020 15:55:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Osteoarthritis- knees | Initial Entry |

1.i Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Sep-01-2020 15:55:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> UNK/UNK/2010 | Initial Entry |

1.i Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Sep-01-2020 15:55:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> YES | Initial Entry |

1.j

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Sep-01-2020 15:56:05 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Line/MH Number 10 : Medical History T Leg Cramps erm: Start Date: UNK/UNK/1 972 Ongoing: YES | Initial Entry |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1.j Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------|---------------|
| Sep-01-2020 15:56:05 (UTC-06:00) Central 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 |
|---|-----------------|---------------------|----------------------------------|---------------|
| Sep-01-2020 15:56:05 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Leg Cramps | Initial Entry |

1.j Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Sep-01-2020 15:56:05 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/1972 | Initial Entry |

1.j Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Sep-01-2020 15:56:05 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

1.k

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Sep-01-2020 15:56:17 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 11 Medical History Recurrent Back pain Term: k pain Start Date: UNK/UNK/2010 Ongoing: YES | Initial Entry |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.k Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------|---------------|
| Sep-01-2020 15:56:17 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 11 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-01-2020 15:56:17 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Recurrent Back pain | Initial Entry |

1.k Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Sep-01-2020 15:56:17 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> UNK/UNK/2010 | Initial Entry |

1.k Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Sep-01-2020 15:56:17 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> YES | Initial Entry |

1.l

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Sep-01-2020 15:56:29 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Line/MH Number 12 : Medical History T Allergic Rhin erm: itis Start Date: UNK/UNK/1 986 Ongoing: YES | Initial Entry |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.1 Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------|---------------|
| Sep-01-2020 15:56:29 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 12 | Initial Entry |

1.1 Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-01-2020 15:56:29 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Allergic Rhinitis | Initial Entry |

1.1 Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Sep-01-2020 15:56:29 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/1986 | Initial Entry |

1.1 Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Sep-01-2020 15:56:29 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|---------------|
| Sep-01-2020 15:56:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/1/2020 | Initial Entry |

2. Weight:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------|---------------|
| Sep-01-2020 15:56:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 255.6 | Initial Entry |

3. Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Sep-01-2020 15:56:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: LB | Initial Entry |

4. Height:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------|---------------|
| Sep-01-2020 15:56:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 67.25 | Initial Entry |

5. Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Sep-01-2020 15:56:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: in | Initial Entry |

6. Body Mass Index:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Sep-01-2020 15:56:57 (UTC-06:00) Central | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 39.7 | Initial Entry |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

| | | | | |
|--------------------|--|--|--|--|
| Time (US & Canada) | | | | |
|--------------------|--|--|--|--|

7.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-01-2020 15:56:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier:: 1 Temperature: 98.7 Temperature Unit: F Temperature Location:: EAR | Initial Entry |

7.a Record Identifier:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Sep-01-2020 15:56:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

7.a Temperature:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------|---------------|
| Sep-01-2020 15:56:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 98.7 | Initial Entry |

7.a Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Sep-01-2020 15:56:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: F | Initial Entry |

7.a Temperature Location:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Sep-01-2020 15:56:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EAR | Initial Entry |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Randomization Date :

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|---------------|
| Sep-01-2020 15:58:02 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/1/2020 | Initial Entry |

2. Randomization Number:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Sep-01-2020 15:58:02 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 248851 | Initial Entry |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

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:** 1019**Site Name:** (1019) Diagnostics Research Group**Subject No:** 10191146**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Data Origin**

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Sep-01-2020 16:24:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Sep-01-2020 16:24:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--|--|
| Sep-01-2020 16:24:53 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Sep-01-2020 16:24:38 (UTC-06:00) Central 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-01-2020 16:24:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Sep/1/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-01-2020 16:24:53 (UTC-06:00) Central | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BP98C0 | 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: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

| | | | | |
|--------------------|--|------------------|--|--|
| Time (US & Canada) | | (b) (4), (b) (6) | | |
|--------------------|--|------------------|--|--|

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Sep-01-2020 16:24:53 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BP98C0 | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-01-2020 16:25:01 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BP98C1 | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Sep-01-2020 16:25:01 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BP98C1 | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-01-2020 16:25:08 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BP98C2 | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Sep-01-2020 16:25:08 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BP98C2 | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|----------------------|-----------------|------------------|--------------------|---------------|
| Sep-01-2020 16:25:26 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

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: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-06:00) Central Time (US & Canada)

(b) (4),
(b) (6)

Sample ID: BPRMD3

5.d Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Sep-01-2020 16:25:26 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BPRMD3 | Initial Entry |

5.e

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Sep-01-2020 16:25:35 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BPRMD4 | Initial Entry |

5.e Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Sep-01-2020 16:25:35 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BPRMD4 | Initial Entry |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (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: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Sep-01-2020 16:25:48 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Sep-01-2020 16:25:48 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--|--|
| Sep-01-2020 16:26:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Sep-01-2020 16:25:48 (UTC-06:00) Central 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-01-2020 16:25:48 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Sep/1/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-01-2020 16:26:04 (UTC-06:00) Central | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BM864N | Initial Entry |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (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: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)

(b) (4), (b) (6)

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Sep-01-2020 16:26:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BM864N | Initial Entry |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Sep-01-2020 15:58:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2. Treatment Name

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Sep-01-2020 15:58:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BLINDED THERAPY | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Sep-01-2020 15:58:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INJECTION | Initial Entry |

4. Dose Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-01-2020 15:58:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/1/2020 14:40 | Initial Entry |

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Sep-01-2020 15:58:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------|---------------|
| Sep-01-2020 15:58:15 (UTC-06:00) Central | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: LEFT | Initial Entry |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

| | | | |
|--------------------|--|------------------|--|
| Time (US & Canada) | | (b) (4), (b) (6) | |
|--------------------|--|------------------|--|

7. Route:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Sep-01-2020 15:58:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Sep-01-2020 15:58:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: THE PROTOCOL SPECIFIED O BSERVATION 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-01-2020 15:58:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Select appropriate response - Reactogenicity diary collection

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-01-2020 15:58:21 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO - REACTOGENICITY E-DI ARY NOT COLLECTED FOR THIS SUBJECT | Initial Entry |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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I. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-22-2020 09:36:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/22/2020 | Initial Entry |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-22-2020 09:41:59 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/22/2020 | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-22-2020 09:41:59 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier:: 1 Temperature: 97.8 Temperature Unit: F Temperature Location:: EAR | Initial Entry |

2.a Record Identifier:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Sep-22-2020 09:41:59 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

2.a Temperature:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------|---------------|
| Sep-22-2020 09:41:59 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 97.8 | Initial Entry |

2.a Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Sep-22-2020 09:41:59 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: F | Initial Entry |

2.a Temperature Location:

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Sep-22-2020 09:41:59 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> EAR | 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:** 1019**Site Name:** (1019) Diagnostics Research Group**Subject No:** 10191146**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Data Origin**

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Sep-22-2020 10:42:47 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Sep-22-2020 10:42:47 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|--|
| Sep-22-2020 10:42:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Sep-22-2020 10:42:47 (UTC-06:00) Central 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-22-2020 10:42:47 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Sep/22/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-22-2020 10:42:57 (UTC-06:00) Central | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BP98MB | 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: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)

(b) (4), (b) (6)

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Sep-22-2020 10:42:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BP98MB | Initial Entry |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Sep-22-2020 09:42:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2. Treatment Name

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Sep-22-2020 09:42:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BLINDED THERAPY | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Sep-22-2020 09:42:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INJECTION | Initial Entry |

4. Dose Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-22-2020 09:42:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/22/2020 07:56 | Initial Entry |

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Sep-22-2020 09:42:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------|---------------|
| Sep-22-2020 09:42:30 (UTC-06:00) Central | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: LEFT | Initial Entry |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

| | | | |
|--------------------|--|------------------|--|
| Time (US & Canada) | | (b) (4), (b) (6) | |
|--------------------|--|------------------|--|

7. Route:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Sep-22-2020 09:42:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Sep-22-2020 09:42:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: THE PROTOCOL SPECIFIED O BSERVATION 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-22-2020 09:42:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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I. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---|
| Oct-31-2020 08:04:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Oct-30-2020 08:41:37 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Form updated. |
| Oct-30-2020 03:31:35 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | DM: The treatment period is defined as 1st vaccination visit through the 1-month post vaccination visit after the 2nd vaccination. Please complete treatment disposition CRF and update date of EOT to match date of blood sample collection date at visit 3. |
| Oct-27-2020 15:36:55 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/27/2020 | Initial Entry |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (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:** 1019**Site Name:** (1019) Diagnostics Research Group**Subject No:** 10191146**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Data Origin**

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Oct-27-2020 15:37:05 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Oct-27-2020 15:37:05 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|--|
| Oct-27-2020 15:37:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Oct-27-2020 15:37:05 (UTC-06:00) Central 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 15:37:05 (UTC-06:00) Central 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 15:37:15 (UTC-06:00) Central | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BR85SM | 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: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

| | | | | |
|--------------------|--|------------------|--|--|
| Time (US & Canada) | | (b) (4), (b) (6) | | |
|--------------------|--|------------------|--|--|

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Oct-27-2020 15:37:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BR85SM | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Oct-27-2020 15:37:23 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BRTM3T | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Oct-27-2020 15:37:23 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BRTM3T | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Oct-27-2020 15:37:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BRTM3V | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Oct-27-2020 15:37:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BRTM3V | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|----------------------|-----------------|------------------|--------------------|---------------|
| Oct-27-2020 15:37:37 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (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: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-06:00) Central Time (US & Canada)

(b) (4),
(b) (6)

Sample ID: BRTM3W

5.d Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Oct-27-2020 15:37:37 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BRTM3W | Initial Entry |

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Completion/Discontinuation/Death :

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Oct-30-2020 08:41:23 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/27/2020 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------------|---------------|
| Oct-30-2020 08:41:23 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: VACCINATION | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------------|---------------|
| Oct-30-2020 08:41:23 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |

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Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Completion/Discontinuation/Death :

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------------|-----------------------------------|--|
| Feb-11-2021 12:17:55 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Query 1: Closed | Response satisfies query |
| Feb-10-2021 07:32:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Initial Entry |
| Feb-10-2021 07:32:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: Dec/17/2020 | Initial Entry |
| Feb-09-2021 23:34:58 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Query 1: Opened | SAE RECON: AER#2020373811, the date of death was reported as 17Dec2020 in Safety database but missing in CRF. Please confirm correct date of death. If safety update is required, please submit a follow-up form. |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Feb-10-2021 07:32:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: FOLLOW-UP | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------------|-----------------------------|---------------|
| Feb-10-2021 07:32:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: DEATH | Initial Entry |

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|--------|
| Oct-27-2020 14:53:20 (UTC-06:00) Central 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: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|--------|
| Nov-20-2020 15:16:38 (UTC-06:00) Central 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: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Category:

| Date | Location | User | Value | Reason |
|--|-----------------|----------------------|-------------------------------------|---------------|
| Oct-27-2020 14:53:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|--|-----------------|----------------------|-------------------------|---------------|
| Oct-27-2020 14:53:20 (UTC-06:00) Central 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 |
|--|-----------------|---------------------|--------------------|---|
| Feb-15-2021 20:09:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 6: Closed | Clinical The composite term was split at the request of Safety for individual coding. |
| Feb-12-2021 17:32:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 6: Opened | CLINQUERY: please confirm that the AEs of "Biliary Cancer Metastatic" and "Metastases to Liver" should be consolidated into one fatal event of "Metastatic Biliary Cancer". Please also update the death detail CRF as appropriate. |
| Feb-12-2021 17:29:34 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 6: Candidate | CLINQUERY: please confirm that "Biliary Cancer Metastatic" and "Metastases to Liver" should be consolidated into one fatal SAE of "Metastatic Biliary |

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Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

| | | | | |
|---|---|---------------------|------------------------------|---|
| | | | | Cancer". Please also update the death detail CRF as appropriate. |
| Feb-08-2021 08:51:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 5: Closed | Response satisfies query |
| Feb-05-2021 12:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 5: Answered | updated SAE sent |
| Feb-01-2021 17:58:59 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 5: Opened | Clinical Please submit a SAE safety update with the treatment course selected for event 'metastatic biliary Cancer' |
| Dec-09-2020 13:00:43 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Closed | Response satisfies query |
| Dec-08-2020 09:33:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Answered | SAE submitted to provide diagnostic procedure |
| Nov-21-2020 17:22:31 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Reissued: Opened | CLINICAL Please submit a safety update with the diagnostic procedure / pathologic diagnosis which demonstrated the primary tumor = biliary cancer |
| Nov-20-2020 16:52:36 | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle | Query 4: Closed | Discrepancy has been closed. |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

| | | | | |
|--|---|-----------------------------|--|--|
| (UTC-06:00) Central Time (US & Canada) | | (b) (4) | sed | |
| Nov-20-2020 15:14:45 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 4: An swere d | changed per query |
| Nov-20-2020 15:14:45 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry : Biliar y Can cer M etastat ic | changed per query |
| Nov-19-2020 14:11:14 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 4: Op ened | Multiple concepts in the term BILIARY CARCINOMA METASTATIC TO LIVER. Split the term into BILIARY CANCER METASTATIC and METASTASES TO LIVER and submit separately. Thank you. |
| Nov-19-2020 09:28:58 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 3: An swere d | updated per PI and SAE follow-up has been submitted to match |
| Nov-19-2020 09:28:58 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry : Biliar y Car cinom a Met astatic | updated per PI and SAE follow-up has been submitted to match |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

| | | | | |
|---|-----------------|------------------------|-------------------|---|
| | | | to Liver | |
| Nov-19-2020 00:13:00 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Opened | Clinical Please split the term, with the primary malignancy of CARCINOMA of UNKOWN PRIMARY on one line; otherwise coding reports this a metastatic liver cancer. Thank you. |
| Nov-14-2020 08:27:31 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | term updated in both database. issue resolved. |
| Nov-13-2020 10:31:10 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry | This is the PIs final reporting diagnosis. Site will not change (as requested in INFORM) to "without metastasis". SAE will be re-submitted with above AE event diagnosis. |
| Nov-13-2020 08:43:06 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Answered | New Information |
| Nov-13-2020 08:43:06 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry | New Information |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

| | | | | |
|---|---|-----------------------|---|--|
| Canada) | | | entiated carcinoma (without metastasis) | |
| Nov-11-2020 05:24:51 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Reissued: Opened | SAE RECON: The term was updated to 'poorly differentiate hepatic carcinoma (without metastasis)'. However, term in AE CRF was poorly differentiated carcinoma metastatic to liver. Please confirm TERM and update AE CRF. |
| Nov-10-2020 07:21:29 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | SAE updated |
| Nov-08-2020 18:43:47 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened | SAE RECON:AER#2020420011 Per the narrative, the poorly differentiated carcinoma was only identified in the liver. Please clarify whether the final diagnosis is poorly differentiate hepatic carcinoma(without metastasis) |
| Nov-02-2020 17:58:45 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 1: Closed | Discrepancy has been closed. |
| Oct-29-2020 11:16:15 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: An | Per PI, can not be split. |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

| | | | | |
|--|---|---|---|---|
| (UTC-06:00) Central Time (US & Canada) | | (b) (4), (b) (6) | swere d | |
| Oct-29-2020 09:32:55 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Sandip Namdeorao Suryawanshi (b) (4) | Query 1: Rei ssued: Opene d | Kindly split the term into POORLY DIFFERENTIATED CARCINOMA METASTATIC and METASTASES TO LIVER and submit separately. Thank you. |
| Oct-28-2020 13:40:12 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: An swere d | Per PI, Term will remain the same |
| Oct-28-2020 06:05:43 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 1: Op ened | Multiple concepts in the term POORLY DIFFERENTIATED CARCINOMA METASTATIC TO LIVER. Split the term into POORLY DIFFERENTIATED CARCINOMA METASTATIC and METASTASES TO LIVER and submit separately. Thank you. |
| Oct-27-2020 14:53:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry : poorly differ entiat ed car cinom a met astatic to live r | Initial Entry |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

4. Start Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Oct-27-2020 14:53:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/27/2020 UNK:UNK | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|-----------------|
| Feb-05-2021 12:33:55 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date Time: Dec/17/2020 UNK:UNK | New Information |
| Oct-27-2020 14:53:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|-------------------------|--|
| Feb-10-2021 14:10:07 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Feb-10-2021 08:46:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | New Information |
| Feb-10-2021 08:46:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 4 | New Information |
| Feb-09-2021 14:17:17 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | CLINQUERY: please clarify if the toxicity grade for Biliary Cancer Metastatic should be reported as 4 (protocol 10.3.3 LIFE-THREATENING: Life-threatening consequences; urgent intervention indicated). |

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Header Text: c4591001

Visit: Logs - Unscheduled

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Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

| | | | | |
|---|-----------------|---------------------|-------------------------|---------------|
| Oct-27-2020 14:53:20 (UTC-06:00) Central 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-05-2021 12:33:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? YES Did this serious event require or prolong hospitalization? NO Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event YES | New Information |

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1019**Subject No:** 10191146**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1019) Diagnostics Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44

| | | | | |
|---|-----------------|--|--------------------------|---|
| Nov-13-2020 10:38:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] [REDACTED] | Query 1: Closed | Safety notified and will continue FU as part of SAE reconciliation process. |
| Nov-13-2020 08:45:26 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Query 1: Answered | per records carcinoma on liver |
| Nov-11-2020 02:25:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] [REDACTED] | Query 1: Reissued:Opened | GPDCLIN: It is unclear if this is a primary hepatocellular carcinoma or another primary tumor that sent a metastasis to the liver. If the later is correct, please clarify what is the primary tumor and ensure AE term is updated as applicable. |
| Nov-05-2020 10:16:58 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Query 1: Answered | on liver |
| Oct-30-2020 08:45:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] [REDACTED] | Query 1: Reissued:Opened | GPDCLIN: AE term suggests that the liver lesion is considered to be a metastasis rather than a primary liver tumor. please confirm and if correct, where is the primary tumor? |
| Oct-29-2020 09:20:54 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Query 1: Answered | Location is Liver |
| Oct-29-2020 03:46:12 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Deleted | Close Auto Query |

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|---|-----------------|--|--------------------------|--|
| Oct-29-2020 03:16:22 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] [REDACTED] | Query 1: Reissued:Opened | GPDCLIN: thank you for your response, please clarify what is the type and location of the primary tumor. |
| Oct-28-2020 13:40:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Candidate | For AE poorly differentiated carcinoma metastatic to liver: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank. |
| Oct-28-2020 13:40:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Transcription Error |

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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 |
|---|-----------------|---------------------|--|---------------------|
| Oct-28-2020 13:40:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <p>Data Entry:</p> <p>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>NO</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>YES</p> | Transcription Error |

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|---|-----------------|---------------------|--------------------------|---|
| Oct-28-2020 11:57:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | GPDCLIN: New metastatic cancer is reported as non-serious AE. Please clarify what is the primary tumor that spread to the liver and consider reporting this malignant cancer also as SAE(i.e. important medical event). else, please clarify. |
| Oct-27-2020 14:53:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 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 |
|---|-----------------|---------------------|--------------------------|---------------|
| Oct-27-2020 14:53:20 (UTC-06:00) Central 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 |
|---|-----------------|---------------------|---|---------------|
| Oct-27-2020 14:53:20 (UTC-06:00) Central 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 |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

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| | | | | |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-27-2020 14:53:20 (UTC-06:00) Central 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 |
|---|-----------------|---------------------|--------------------------|---------------|
| Oct-27-2020 14:53:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Oct-27-2020 14:53:20 (UTC-06:00) Central 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 |
|---|-----------------|---------------------------|-----------------|--|
| Feb-05-2021 12:34:23 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 5: Closed | Close Auto Query |
| Feb-05-2021 12:33:55 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 4: Closed | Close Auto Query |
| Feb-05-2021 12:33:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 5: Opened | Response to "What was the outcome of this adverse event?" is 'Fatal' but Date of Collection / Notification of Death on the Death Details form is not completed. Please review and update as appropriate. |
| Feb-05-2021 12:33:30 (UTC-06:00) Central Time (US | ACV0PFEINFP6000 | auto query (autoquery) | Query 4: Opened | For AE Biliary Cancer Metastatic: Response to "What was the outcome of this adverse event?" is 'Fatal' but "Is the adverse event still ongoing?" |

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|---|-----------------|---------------------------|--|--|
| & Canada) | | | | is marked 'Yes'. |
| Feb-05-2021 12:33:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: FATAL | New Information |
| Nov-06-2020 05:05:06 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | Response satisfies query |
| Nov-05-2020 09:54:05 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | SAE Submitted to reflect not recovered/resolved |
| Oct-30-2020 05:40:29 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Reissued: Opened | SAE RECON:AER#2020420011,outcome was reported as UNKNOWN to 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. |
| Oct-29-2020 09:20:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 3: Closed | Close Auto Query |
| Oct-29-2020 09:20:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT RECOVERE D/NOT RESOLVE D | Transcription Error |
| Oct-29-2020 09:20:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 3: Opened | For AE poorly differentiated carcinoma metastatic to liver: 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 |

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|---|-----------------|---------------------------|-------------------------------|--|
| | | | | marked "Yes". |
| Oct-29-2020 09:20:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Answered | Initial Entry |
| Oct-29-2020 09:20:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNKNOWN | Initial Entry |
| Oct-29-2020 01:09:35 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened | DM: The response for "What was the outcome of this adverse event?" is missing. Kindly review and update. |
| Oct-27-2020 14:57:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Oct-27-2020 14:57:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Transcription Error |
| Oct-27-2020 14:53:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | For AE poorly differentiated carcinoma metastatic to liver: 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". |
| Oct-27-2020 14:53:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNKNOWN | Initial Entry |

14. Did the adverse event cause the subject to be discontinued from the study?

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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---------------------------|--|
| Feb-10-2021 12:14:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Feb-10-2021 08:46:35 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | New Information |
| Feb-10-2021 08:46:35 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | New Information |
| Feb-09-2021 06:57:58 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | DM: AE Outcome is FATAL but "Did the adverse event cause the subject to be discontinued from the study" is marked as No. Kindly review and update, else clarify. Thank you. |
| Oct-27-2020 14:53:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

15. Serious Adverse Event Number: For Pfizer Use Only

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|---------------|
| Oct-29-2020 03:46:12 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 2020420011 | Initial Entry |

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Subject Initials: ---

Generated By: (b) (4)

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1. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Nov-20-2020 15:16:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Nov-20-2020 15:16:38 (UTC-06:00) Central 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 |
|---|-----------------|---------------------|---|---------------|
| Nov-20-2020 15:16:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Metastases to Liver | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-20-2020 15:16:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/27/2020 UNK:UNK | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|------------------|
| Feb-10-2021 08:42:51 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Feb-10-2021 08:42:51 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date Time: Dec/17/2020 UNK:UNK | New Information |

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|---|-----------------|---------------------------|---------------------------|--|
| Feb-10-2021 07:32:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | 'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please review and update as appropriate. |
| Nov-20-2020 15:16:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|-------------------------|--|
| Feb-10-2021 14:16:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Feb-10-2021 08:43:07 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | New Information |
| Feb-10-2021 08:43:07 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 4 | New Information |
| Feb-09-2021 14:17:58 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | CLINQUERY: please clarify if the toxicity grade for Metastases to Liver should be reported as 4 (protocol 10.3.3 LIFE-THREATENING: Life-threatening consequences; urgent intervention indicated). |
| Nov-20-2020 15:16:38 (UTC-06:00) Central 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

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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-14-2021 09:17:41 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | Response satisfies query |
| Feb-12-2021 11:13:43 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Answered | Transcription Error |
| Feb-12-2021 11:13:43 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? YES Did this serious event require or prolong hospitalization? NO Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event YES | Transcription Error |

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|---|-----------------|--|--|--|
| Feb-12-2021 11:03:45 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] [REDACTED] | Query 2: Opened | GPDCLIN: Outcome of AE is reported as fatal however, the answer to the question: Did this serious event result in death? is NO. please review and update as applicable. Else, please clarify. |
| Nov-23-2020 03:58:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Nov-20-2020 15:16:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | For AE Metastases to Liver: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank. |
| Nov-20-2020 15:16:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: 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? NO Did this serious event result in persistent or significant disability/incapacity? | Initial Entry |

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|--|--|--|---|--|
| | | | NO | |
| | | | Is this serious event life threatening? | |
| | | | NO | |
| | | | Other medically important serious event | |
| | | | YES | |

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 |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-20-2020 15:16:38 (UTC-06:00) Central 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-08-2021 12:26:07 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Feb-05-2021 09:04:44 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Transcription Error |
| Feb-05-2021 09:04:44 (UTC-06:00) Central 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> metastatic biliary cancer | Transcription Error |
| Feb-01-2021 17:51:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | Clinical Other reason for Mets to Liver is 'found through checkup'; |

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

| | | | | |
|--|-----------------|---------------------|--|---|
| | | | | however, SAE reports the mets are due to metastatic biliary cancer. Please review other cause of mets in liver, and update as appropriate |
| Nov-20-2020 15:16:38 (UTC-06:00) Central 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> found through medical check-up | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-20-2020 15:16:38 (UTC-06:00) Central 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 |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-20-2020 15:16:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-20-2020 15:16:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

13. What was the outcome of this adverse event?:

| |
|--|
| |
|--|

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--|--|
| Feb-10-2021 08:43:24 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Feb-10-2021 08:43:24 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: FATAL | New Information |
| Feb-10-2021 08:42:51 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | For AE Metastases to Liver: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present. |
| Nov-20-2020 15:16:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT RECOVERED/NOT RES OLVED | Initial Entry |

14. Did the adverse event cause the subject to be discontinued from the study?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|-------------------|---|
| Feb-16-2021 14:14:35 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Feb-16-2021 13:30:13 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Closed | Clinical following up in another query |
| Feb-16-2021 11:23:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Answered | updated to respond to query |
| Feb-16-2021 11:16:35 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 3: Opened | More than 1 AE for this patient has "Did the adverse event cause the subject to be discontinued from the study?" marked as 'Yes'. |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

| | | | | |
|---|-----------------|---------------------------|---------------------------|---|
| Feb-16-2021 11:16:35 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | New Information |
| Feb-16-2021 11:16:35 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | New Information |
| Feb-14-2021 09:19:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Opened | GPDCLIN: Please clarify your response as the answer to this question is NO while AE is fatal. |
| Feb-12-2021 11:15:02 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Closed | Close Auto Query |
| Feb-12-2021 11:15:02 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Transcription Error |
| Feb-12-2021 11:12:23 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Opened | More than 1 AE for this patient has "Did the adverse event cause the subject to be discontinued from the study?" marked as 'Yes'. |
| Feb-12-2021 11:12:23 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | New Information |
| Feb-12-2021 11:12:23 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | New Information |
| Feb-12-2021 11:05:19 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | GPDCLIN: Outcome of this AE is fatal however, the answer to the question whether the AE caused study discontinuation is NO. Please review and update as |

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Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

| | | | | |
|---|-----------------|---------------------|--------------------------|------------------------|
| | | | | applicable or clarify. |
| Nov-20-2020 15:16:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

15. Serious Adverse Event Number: For Pfizer Use Only

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|---------------|
| Nov-23-2020 03:58:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 2020420011 | Initial Entry |

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: DEATH DETAILS CODED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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I. Date of Collection / Notification of Death:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|-------------------|--|
| Feb-15-2021 17:48:53 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Feb-10-2021 14:05:39 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | Response satisfies query |
| Feb-10-2021 12:26:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Closed | Response satisfies query |
| Feb-10-2021 08:45:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | FUP CRF has been updated. |
| Feb-10-2021 08:45:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | Changed data per query |
| Feb-10-2021 08:44:58 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Answered | Site was not made aware of Subject's passing until this date. |
| Feb-10-2021 07:32:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 3: Opened | Date of Collection / Notification of Death is greater than the Date of Completion/Discontinuation /Death on the Disposition form 17/Dec/2020. Please review and update as appropriate |
| Feb-09-2021 14:15:14 (UTC-06:00) Central | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened | CLINQUERY: Death form is entered but disposition follow-up (FUP) is not |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

| | | | | |
|--|-----------------|---------------------|----------------------------------|--|
| Time (US & Canada) | | | | complete. Please verify and update the FUP form, else clarify. |
| Feb-08-2021 17:43:58 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | ClinQuery: Please complete Follow up CRF. |
| Feb-05-2021 12:34:23 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Feb/5/2021 | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------------|
| Feb-08-2021 09:28:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Cause of Death Status: PRIMARY CAUSE OF DEATH Cause of Death: METASTASES T O LIVER | Transcription Error |
| Feb-05-2021 12:34:45 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Cause of Death Status: PRIMARY CAUSE OF DEATH Cause of Death: Biliary Carcinoma Metastatic to Liver | Initial Entry |

2.a Cause of Death Status:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Feb-05-2021 12:34:45 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: PRIMARY CAUSE OF DEATH | Initial Entry |

2.a Cause of Death:

| Date | Location | User | Value | Reason |
|--|---|-----------------------------|-----------------|------------------------------|
| Feb-08-2021 10:48:19 (UTC-06:00) Central Time | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 1: Closed | Discrepancy has been closed. |

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Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: DEATH DETAILS CODED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

| | | | | |
|---|---|-----------------------------|---|---|
| (US & Canada) | | | | |
| Feb-08-2021 09:28:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Ans wered | Transcription Error |
| Feb-08-2021 09:28:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: METASTAS ES TO LIVE R | Transcription Error |
| Feb-05-2021 15:57:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 1: Ope ned | Multiple concepts in the term BILIARY CARCINOMA METASTATIC TO LIVER. Split the term into BILIARY CANCER METASTATIC and METASTASES TO LIVER and submit separately. Thank you. |
| Feb-05-2021 12:34:45 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Biliary Carci noma Metast atic to Liver | Initial Entry |

2.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------------|
| Feb-08-2021 09:28:13 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Cause of D SECONDARY C eath Status AUSE OF DEAT : H | Transcription Error |

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: DEATH DETAILS CODED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

| | | | | |
|--|-----------------|---------------------|---|---------------|
| | | | Cause of Death: BILIARY CANCER METASTATIC | |
| Feb-08-2021 09:27:59 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Cause of Death Status: PRIMARY CAUSE OF DEATH : Cause of Death: BILIARY CANCER METASTATIC | Initial Entry |

2.b Cause of Death Status:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------------|--|---|
| Feb-08-2021 09:28:13 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Feb-08-2021 09:28:13 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: SECONDARY CAUSE OF DEATH | Transcription Error |
| Feb-08-2021 09:27:59 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | There is more than one primary cause of death reported. Please update so that there is one Primary Cause of death, noting that there can be multiple Secondary Causes of death. |
| Feb-08-2021 09:27:59 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: PRIMARY CAUSE OF DEATH | Initial Entry |

2.b Cause of Death:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Feb-08-2021 09:27:59 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BILIARY CANCER METASTATIC | Initial Entry |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1019

Subject No: 10191146

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1019) Diagnostics Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Subject Status

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Feb-10-2021 07:32:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DISCONTINUED | Initial Entry |
| Oct-30-2020 08:41:23 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: FOLLOW-UP | Initial Entry |
| Sep-01-2020 15:58:02 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ENROLLED/RANDOMIZED | Initial Entry |
| Sep-01-2020 15:53:07 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SCREENED | Initial Entry |

2. Subject Status Date

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------------|---------------|
| Feb-10-2021 07:32:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Dec/17/2020 | Initial Entry |
| Oct-30-2020 08:41:23 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Oct/27/2020 | Initial Entry |
| Sep-01-2020 15:58:02 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sep/1/2020 | Initial Entry |
| Sep-01-2020 15:53:07 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sep/1/2020 | Initial Entry |

090177e196ae3e24\Final\Final On: 01-Apr-2021 04:46 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1019

Site Name: (1019) Diagnostics Research Group

Subject No: 10191146

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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I. Casebook Signature

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-16-2020 13:46:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Click Here to Enable | Initial Entry |