

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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

[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 |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Informed Consent

| | | |
|----|--------------|---|
| 1. | Consent Was: | OBTAINED Date Written Consent Obtained Sep/4/2020 |
|----|--------------|---|

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Demography

| | | |
|----|---------------------------------|--|
| 1. | Subject ID | [10681111] |
| 2. | Birth Date: | (b) (6)/1957 |
| 3. | Sex: | FEMALE |
| 4. | Ethnicity: | NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN |
| 5. | Race: (Check X all that apply): | WHITE |
| 6. | Racial Designation: | |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|------------|
| 1. | Date of Visit | Sep/4/2020 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1068

Subject No: 10681111

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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 _____ |
|----|--|-------------------------|

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681111

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Disposition - Screening

| | | |
|----|--|------------|
| 1. | Date of Completion/Discontinuation/Death | Sep/4/2020 |
| 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: 1068

Subject No: 10681111

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

Form Comments

Medical History Details

| | | |
|----|--|--------------------------------|
| 1. | Line/MH Number: | Not Applicable _____ [] |
| | Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies: | Not Applicable _____ [] |
| | Start Date: | Not Applicable _____ // |
| | Ongoing: | Not Applicable _____ |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Vital Signs

| | | |
|----|------------------|------------|
| 1. | Date: | Sep/4/2020 |
| 2. | Weight: | [70.9] |
| 3. | Unit: | kg |
| 4. | Height: | [149.9] |
| 5. | Unit: | cm |
| 6. | Body Mass Index: | [31.6] |

Vital Signs Details

| | | |
|-----|-----------------------|-------------|
| 7.a | Record Identifier: | 1 |
| | Temperature: | [98.3] |
| | Unit: | F |
| | Temperature Location: | ORAL CAVITY |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1068

Subject No: 10681111

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Lab Urinalysis

| | | |
|----|---------------------------------------|--------------|
| 1. | Lab Panel: | URINALYSIS |
| 2. | Lab Sub-Panel: | PREGNANCY |
| 3. | Collection Date: | Sep/4/2020 |
| 4. | Laboratory Name and Address (Derived) | [STUDY SITE] |
| 5. | Specimen Type: | URINE |

Lab Result

| | | |
|-----|-------------|-------------------------------|
| 6.a | Sponsor ID: | [113] |
| | Test: | Choriogonadotropin Beta_PX113 |
| | Result: | NEGATIVE |
| | Not Done: | |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681111

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Disposition

| | | |
|----|-----------------------|------------|
| 1. | Randomization Date : | Sep/4/2020 |
| 2. | Randomization Number: | [252643] |
| 3. | Randomization Group: | [] |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|--|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Sep/4/2020 |
| 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 | [BNZPM6] |
| 5.b | Sample ID | [BNZPM7] |
| 5.c | Sample ID | [BNZPM8] |
| 5.d | Sample ID | [BPHSG6] |
| 5.e | Sample ID | [BPHSG7] |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|--|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Sep/4/2020 |
| 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 | [BNZPM4] |
|-----|-----------|----------|

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1068

Subject No: 10681111

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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/4/2020 16:34 |
| 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 |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1068

Subject No: 10681111

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

Header Text: c4591001

Visit: V2_VAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Sep/25/2020 |
| 2. | Erroneous Visit | |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1068

Subject No: 10681111

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Vital Signs

| | | |
|----|-------|-------------|
| 1. | Date: | Sep/25/2020 |
|----|-------|-------------|

Vital Signs Details

| | | |
|-----|-----------------------|-------------|
| 2.a | Record Identifier: | 1 |
| | Temperature: | [98.7] |
| | Unit: | F |
| | Temperature Location: | ORAL CAVITY |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 21-Aug-2020 02:49**Site No:** 1068**Subject No:** 10681111**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1068) Bozeman Health Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:05[Form Comments](#)[eCRF Audit Trail History](#)**Lab Urinalysis**

| | | | |
|----|---------------------------------------|--------------------------------|--------------------------|
| 1. | Lab Panel: | Not Applicable _____ | Comments |
| 2. | Lab Sub-Panel: | Not Applicable _____ | Comments |
| 3. | Collection Date: | Not Applicable _____ // | Comments |
| 4. | Laboratory Name and Address (Derived) | Not Applicable _____ [] | Comments |
| 5. | Specimen Type: | Not Applicable _____ | Comments |

Lab Result

| | | | |
|-----|-------------|--|--------------------------|
| 6.a | Sponsor ID: | Not Applicable _____ [] | Comments |
| | Test: | Not Applicable _____ Choriogonadotropin Beta_PX113 | |
| | Result: | Not Applicable _____ | Comments |
| | Not Done: | Not Applicable _____ | Comments |

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1068**Site Name:** (1068) Bozeman Health Clinical Research**Subject No:** 10681111**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:05[eCRF Audit Trail History](#)**Electronic Sample Tracking**

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Sep/25/2020 |
| 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 | [BNZPT8] |
|-----|-----------|----------|

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1068

Subject No: 10681111

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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/25/2020 16:56 |
| 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 |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1068 **Site Name:** (1068) Bozeman Health Clinical Research

Subject No: 10681111 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:05

[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: 1068 **Site Name:** (1068) Bozeman Health Clinical Research

Subject No: 10681111 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:05

[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 | [BNZP7T] |
| 5.b | Sample ID | [BNVXJG] |
| 5.c | Sample ID | [BNVXJH] |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681111

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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: 1068

Subject No: 10681111

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681111

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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: 1068

Subject No: 10681111

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681111

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

Date of Visit

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

Header Text: c4591001

Visit: V6_MONTH24_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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 Version: 20-Feb-2021 02:17

Site No: 1068

Subject No: 10681111

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Not Started

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (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:** 1068**Site Name:** (1068) Bozeman Health Clinical Research**Subject No:** 10681111**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:05**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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Illness Details

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

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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Unplanned - New Unscheduled **Form:** DATE OF VISIT
Visit

Form Version: 22-Apr-2020 21:02 **Form Status:** Not Started

Site No: 1068 **Site Name:** (1068) Bozeman Health Clinical Research

Subject No: 10681111 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:05

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: 1068 **Site Name:** (1068) Bozeman Health Clinical Research

Subject No: 10681111 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:05

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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

[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: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Disposition - Follow-Up

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB **Form:** DATE OF VISIT - REPEAT SWAB
- New Unscheduled Visit

Form Version: 10-Oct-2020 15:57 **Form Status:** Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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: 1068 **Site Name:** (1068) Bozeman Health Clinical Research

Subject No: 10681111 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:05

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

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

| # | Category | AE Identifier | Adverse Event | Start Date | Is the Adverse Event Still Ongoing | Form Instance |
|----|---------------|---------------|--|-----------------------|--|---------------------------------|
| 1. | ADVERSE EVENT | 1 | Swollen Cervical Lymph Nodes bilateral | Sep/5/2020 UNK:UNK | NO End Date Time: Sep/7/2020 UNK:UNK | Repeating Pages |
| 2. | ADVERSE EVENT | 2 | Injection Site Pain | Sep/5/2020 UNK:UNK | NO End Date Time: Sep/7/2020 UNK:UNK | Repeating Pages |
| 3. | ADVERSE EVENT | 3 | Sneezing | Sep/5/2020 UNK:UNK | NO End Date Time: Sep/7/2020 UNK:UNK | Repeating Pages |
| 4. | ADVERSE EVENT | 4 | Rhinorrhea | Sep/5/2020 UNK:UNK | NO End Date Time: Sep/7/2020 UNK:UNK | Repeating Pages |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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Adverse Event Report

| | | |
|----|--|--|
| 1. | Category: | ADVERSE EVENT |
| 2. | AE ID: | [1] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [Swollen Cervical Lymph Nodes bilateral] |
| 4. | Start Date Time: | Sep/5/2020 UNK:UNK |
| 5. | Is the adverse event still ongoing? | NO End Date Time: Sep/7/2020 UNK:UNK |
| 6. | Toxicity Grade: | 1 |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

| | | |
|-----|---|----------------|
| 7. | Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). | NO |
| 8. | Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log. | NO |
| 9. | Is this event related to study treatment: | RELATED |
| 10. | Latest Action Taken with Study Treatment: | NOT APPLICABLE |
| 11. | Was a Concomitant Medication given? | NO |
| 12. | Was a Non-Drug Treatment given? | NO |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

| | | |
|-----|--|--------------------|
| 13. | What was the outcome of this adverse event?: | RECOVERED/RESOLVED |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | NO |
| 15. | Serious Adverse Event Number: For Pfizer Use Only | [] |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681111

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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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) | [Injection Site Pain] |
| 4. | Start Date Time: | Sep/5/2020 UNK:UNK |
| 5. | Is the adverse event still ongoing? | NO End Date Time: Sep/7/2020 UNK:UNK |
| 6. | Toxicity Grade: | 1 |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

| | | |
|-----|---|----------------|
| 7. | Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). | NO |
| 8. | Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log. | NO |
| 9. | Is this event related to study treatment: | RELATED |
| 10. | Latest Action Taken with Study Treatment: | NOT APPLICABLE |
| 11. | Was a Concomitant Medication given? | NO |
| 12. | Was a Non-Drug Treatment given? | NO |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

| | | |
|-----|--|--------------------|
| 13. | What was the outcome of this adverse event?: | RECOVERED/RESOLVED |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | NO |
| 15. | Serious Adverse Event Number: For Pfizer Use Only | [] |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681111

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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Adverse Event Report

| | | |
|----|--|--|
| 1. | Category: | ADVERSE EVENT |
| 2. | AE ID: | [3] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [Sneezing] |
| 4. | Start Date Time: | Sep/5/2020 UNK:UNK |
| 5. | Is the adverse event still ongoing? | NO End Date Time: Sep/7/2020 UNK:UNK |
| 6. | Toxicity Grade: | 1 |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681111

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

| | | |
|-----|---|----------------|
| 7. | Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). | NO |
| 8. | Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log. | NO |
| 9. | Is this event related to study treatment: | RELATED |
| 10. | Latest Action Taken with Study Treatment: | NOT APPLICABLE |
| 11. | Was a Concomitant Medication given? | NO |
| 12. | Was a Non-Drug Treatment given? | NO |

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

| | | |
|-----|--|--------------------|
| 13. | What was the outcome of this adverse event?: | RECOVERED/RESOLVED |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | NO |
| 15. | Serious Adverse Event Number: For Pfizer Use Only | [] |

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681111

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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Adverse Event Report

| | | |
|----|--|--|
| 1. | Category: | ADVERSE EVENT |
| 2. | AE ID: | [4] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [Rhinorrhea] |
| 4. | Start Date Time: | Sep/5/2020 UNK:UNK |
| 5. | Is the adverse event still ongoing? | NO End Date Time: Sep/7/2020 UNK:UNK |
| 6. | Toxicity Grade: | 1 |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

| | | |
|-----|---|----------------|
| 7. | Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). | NO |
| 8. | Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log. | NO |
| 9. | Is this event related to study treatment: | RELATED |
| 10. | Latest Action Taken with Study Treatment: | NOT APPLICABLE |
| 11. | Was a Concomitant Medication given? | NO |
| 12. | Was a Non-Drug Treatment given? | NO |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

| | | |
|-----|--|--------------------|
| 13. | What was the outcome of this adverse event?: | RECOVERED/RESOLVED |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | NO |
| 15. | Serious Adverse Event Number: For Pfizer Use Only | [] |

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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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 | [] |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON
STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

| # | 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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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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: | // |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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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? | |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

[Back to Form](#)

Radiation Treatment

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

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

[Back to Form](#)

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Lab Urinalysis

| | | |
|----|---------------------------------------|-----|
| 1. | Lab Panel: | |
| 2. | Lab Sub-Panel: | |
| 3. | Collection Date: | // |
| 4. | Laboratory Name and Address (Derived) | [] |
| 5. | Specimen Type: | |

Lab Result

| | | |
|----|-------------|-----|
| 6. | Sponsor ID: | [] |
| | Test: | |
| | Result: | |
| | Not Done: | |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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? | |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Contact Outcome

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - **Form:** DATE OF VISIT
Unscheduled

Form Version: 22-Apr-2020 21:02 **Form Status:** Not Started

Site No: 1068 **Site Name:** (1068) Bozeman Health Clinical Research

Subject No: 10681111 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:05

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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

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:** 1068**Site Name:** (1068) Bozeman Health Clinical Research**Subject No:** 10681111**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:05**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 - **Form:** DATE OF VISIT
Unscheduled

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1068 **Site Name:** (1068) Bozeman Health Clinical Research

Subject No: 10681111 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

| Date of Visit | | |
|---------------|-----------------|-------------|
| 1. | Date of Visit | Dec/18/2020 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION
Unscheduled

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen, Verified

Site No: 1068 **Site Name:** (1068) Bozeman Health Clinical Research

Subject No: 10681111 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Treatment Unblinded

| | | |
|----|--------------------------------|---|
| 1. | Date Treatment Unblinded : | Dec/18/2020 |
| 2. | Primary Reason for Unblinding: | ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION |

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Subject Status

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

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

[Audit Trail](#)

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

- CRF_Sign

| Name | Signature Meaning | Date | Type | Action |
|---------------|-------------------|---|------|--------|
| Andrew Gentry | Approved | Jan-22-2021 12:11:06 (UTC-07:00) Mountain Time (US & Canada) | BOOK | Signed |

Affidavit:

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

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

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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| Item | Date | User | Comment |
|------|---|---------------------|----------------|
| Form | Sep-04-2020 16:58:15 (UTC-07:00) Mountain Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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| Item | Date | User | Comment |
|------|---|---------------------|----------------|
| Form | Sep-04-2020 17:20:43 (UTC-07:00) Mountain Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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| Item | Date | User | Comment |
|------|---|---------------------|--|
| Form | Sep-25-2020 17:12:28 (UTC-07:00) Mountain Time (US & Canada) | (b) (4), (b) (6) | Post Menopause <hr/> Not Applicable |

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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| Item | Date | User | Comment |
|------|---|---------------------|--|
| 1 | Sep-25-2020 17:12:28 (UTC-07:00) Mountain Time (US & Canada) | (b) (4), (b) (6) | Post Menopause <hr/> Not Applicable |

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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| Item | Date | User | Comment |
|------|---|---------------------|--|
| 2 | Sep-25-2020 17:12:28 (UTC-07:00) Mountain Time (US & Canada) | (b) (4), (b) (6) | Post Menopause <hr/> Not Applicable |

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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| Item | Date | User | Comment |
|------|---|---------------------|----------------|
| 3 | Sep-25-2020 17:12:28 (UTC-07:00) Mountain Time (US & Canada) | (b) (4), (b) (6) | Post Menopause |
| | | | Not Applicable |

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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| Item | Date | User | Comment |
|------|---|---------------------|--|
| 4 | Sep-25-2020 17:12:28 (UTC-07:00) Mountain Time (US & Canada) | (b) (4), (b) (6) | Post Menopause <hr/> Not Applicable |

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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| Item | Date | User | Comment |
|------|---|---------------------|--|
| 5 | Sep-25-2020 17:12:28 (UTC-07:00) Mountain Time (US & Canada) | (b) (4), (b) (6) | Post Menopause <hr/> Not Applicable |

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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| Item | Date | User | Comment |
|------|---|---------------------|--|
| 6.a | Sep-25-2020 17:12:28 (UTC-07:00) Mountain Time (US & Canada) | (b) (4), (b) (6) | Post Menopause <hr/> Not Applicable |

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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| Item | Date | User | Comment |
|------|---|---------------------|--|
| 6.a | Sep-25-2020 17:12:28 (UTC-07:00) Mountain Time (US & Canada) | (b) (4), (b) (6) | Post Menopause <hr/> Not Applicable |

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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| Item | Date | User | Comment |
|------|---|---------------------|--|
| 6.a | Sep-25-2020 17:12:28 (UTC-07:00) Mountain Time (US & Canada) | (b) (4), (b) (6) | Post Menopause <hr/> 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, Signed, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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

- CRF_Sign

| Name | Signature Meaning | Date | Type | Action |
|---------------|-------------------|---|------|--------|
| Andrew Gentry | Approved | Jan-22-2021 12:11:06 (UTC-07:00) Mountain Time (US & Canada) | BOOK | Signed |

Affidavit:

By my dated signature below, I, AndrewGentry, 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.

| | | | | |
|-----------------|-----|---|--|-----------------------------------|
| Emily Anglemyer | N/A | Dec-18-2020 12:22:12 (UTC-07:00) Mountain Time (US & Canada) | | Edit - All signatures invalidated |
|-----------------|-----|---|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|---------------|----------|---|------|--------|
| Andrew Gentry | Approved | Nov-02-2020 18:28:11 (UTC-07:00) Mountain Time (US & Canada) | BOOK | Signed |
|---------------|----------|---|------|--------|

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

Affidavit:

By my dated signature below, I, AndrewGentry, 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.

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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1. Select appropriate response - Protocol version

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Sep-04-2020 16:54:54 (UTC-07:00) Mountain 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-04-2020 16:54:54 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: STAGE 3 COHORTS | Initial Entry |

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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1. Consent Was:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Sep-04-2020 16:56:31 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: OBTAINED Date Written Consent Obtained Sep/4/2020 | Initial Entry |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1068

Subject No: 10681111

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[Back to Form](#)

1. Subject ID

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------------|--------------------------------------|
| Sep-04-2020 16:21:35 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 10681111 | Item copied from previous form |

2. Birth Date:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|------------------------------------|---------------------|
| Sep-04-2020 16:21:31 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: (b) (6)/1957 | Enrollment Entry |

3. Sex:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Sep-04-2020 16:57:40 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: FEMALE | Initial Entry |

4. Ethnicity:

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

| | | | | |
|--|-----------------|---------------------|---|---------------|
| Sep-04-2020 16:57:40 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT HISPANIC OR LATINO(A) OR OF S PANISH ORIGIN | Initial Entry |
|--|-----------------|---------------------|---|---------------|

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------|---------------|
| Sep-04-2020 16:57:40 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: WHITE | Initial Entry |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681111

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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1. Date of Visit

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------------|---------------|
| Sep-04-2020 16:58:03 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/4/2020 | Initial Entry |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681111

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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1. Date of Completion/Discontinuation/Death

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------------|---------------|
| Sep-04-2020 16:59:14 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/4/2020 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Sep-04-2020 16:59:14 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SCREENING | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------------|---------------|
| Sep-04-2020 16:59:14 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1068

Subject No: 10681111

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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1. Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------------|---------------|
| Sep-04-2020 17:00:38 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/4/2020 | Initial Entry |

2. Weight:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------|---------------|
| Sep-04-2020 17:00:38 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 70.9 | Initial Entry |

3. Unit:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-04-2020 17:00:38 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: kg | Initial Entry |

4. Height:

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

| | | | | |
|--|-----------------|---------------------|-----------------------------|---------------|
| Sep-04-2020 17:00:38 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 149.9 | Initial Entry |
|--|-----------------|---------------------|-----------------------------|---------------|

5. Unit:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-04-2020 17:00:38 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: cm | Initial Entry |

6. Body Mass Index:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Sep-04-2020 17:00:38 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 31.6 | Initial Entry |

7.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Sep-04-2020 17:00:38 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier:: 1 Temperature: 98.3 | Initial Entry |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

| | | | | |
|--|--|--|--|--|
| | | | Temperature Unit: Temperature Location: ORAL CAVITY : Y | |
|--|--|--|--|--|

7.a Record Identifier:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Sep-04-2020 17:00:38 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

7.a Temperature:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------|---------------|
| Sep-04-2020 17:00:38 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 98.3 | Initial Entry |

7.a Unit:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Sep-04-2020 17:00:38 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: F | Initial Entry |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

7.a Temperature Location:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Sep-04-2020 17:00:38 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ORAL CAVITY | Initial Entry |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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1. Lab Panel:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Sep-04-2020 17:01:18 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: URINALYSIS | Initial Entry |

2. Lab Sub-Panel:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Sep-04-2020 17:01:18 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: PREGNANCY | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------------|---------------|
| Sep-04-2020 17:01:18 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/4/2020 | Initial Entry |

4. Laboratory Name and Address (Derived)

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

| | | | | |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Sep-04-2020 17:01:18 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: STUDY SITE | Initial Entry |
|--|-----------------|-------------------------|----------------------------------|---------------|

5. Specimen Type:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Sep-04-2020 17:01:18 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: URINE | Initial Entry |

6.a

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Sep-04-2020 17:01:18 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor- 113 Defined I dentifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: NEGATIV E Not Done :: | Initial Entry |

6.a Sponsor ID:

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------|---------------|
| Sep-04-2020 17:01:18 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 113 | Initial Entry |

6.a Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Sep-04-2020 17:01:18 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Choriogonadotropin B eta_PX113 | Initial Entry |

6.a Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Sep-04-2020 17:01:18 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEGATIVE | Initial Entry |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681111

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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1. Randomization Date :

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------------|---------------|
| Sep-04-2020 17:01:53 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/4/2020 | Initial Entry |

2. Randomization Number:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Sep-04-2020 17:01:53 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 252643 | Initial Entry |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1068

Subject No: 10681111

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Sep-04-2020 17:02:15 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Sep-04-2020 17:02:15 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|-----------------|-------------------------------------|
| Sep-08-2020 10:16:23 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Sep-07-2020 01:07:07 (UTC-07:00) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | 'Sample Collected?' is Yes, however |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

| | | | | |
|--|-----------------|---------------------------|--|--|
| Mountain Time (US & Canada) | | | | no barcodes are entered. Please review and correct as appropriate. |
| Sep-04-2020 17:02:15 (UTC-07:00) Mountain 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-04-2020 17:02:15 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Sep/4/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Sep-08-2020 10:16:23 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID BNZPM : 6 | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

| | | | | |
|--|-----------------|---------------------|------------------------------|---------------|
| Sep-08-2020 10:16:23 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BNZPM6 | Initial Entry |
|--|-----------------|---------------------|------------------------------|---------------|

5.b

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Sep-08-2020 10:16:35 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID BNZPM : 7 | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Sep-08-2020 10:16:35 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BNZPM7 | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Sep-08-2020 10:16:51 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID BNZPM : 8 | Initial Entry |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

5.c Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Sep-08-2020 10:16:51 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BNZPM8 | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------------|--|---------------|
| Oct-21-2020 15:01:03 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | Emily Anglemyer (b) (4) | Data Entry: Sample I BPHS D: G6 | Initial Entry |

5.d Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------------|------------------------------|---------------|
| Oct-21-2020 15:01:03 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | Emily Anglemyer (b) (4) | Data Entry: BPHSG6 | Initial Entry |

5.e

| Date | Location | User | Value | Reason |
|-------------------------|-----------------|--------------------|--|---------------|
| Oct-21-2020 15:01:10 | ACV0PFEINFP6000 | Emily Anglemyer | Data Entry: Sample I BPHS | Initial Entry |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

| | | | | |
|---|--|---------|--------------|--|
| (UTC-07:00) Mountain Time (US & Canada) | | (b) (4) | D: G7 | |
|---|--|---------|--------------|--|

5.e Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------------|------------------------------|---------------|
| Oct-21-2020 15:01:10 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | Emily Anglemyer (b) (4) | Data Entry: BPHSG7 | Initial Entry |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Sep-04-2020 17:02:30 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Sep-04-2020 17:02:30 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|-----------------|-------------------------------------|
| Sep-08-2020 10:17:07 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Sep-07-2020 01:07:48 (UTC-07:00) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | 'Sample Collected?' is Yes, however |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (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:** 1068**Site Name:** (1068) Bozeman Health Clinical Research**Subject No:** 10681111**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:05

| | | | | |
|--|-----------------|---------------------------|--|--|
| Mountain Time (US & Canada) | | | | no barcodes are entered. Please review and correct as appropriate. |
| Sep-04-2020 17:02:30 (UTC-07:00) Mountain 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-04-2020 17:02:30 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Sep/4/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Sep-08-2020 10:17:07 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID BNZPM : 4 | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

| | | | | |
|--|-----------------|---------------------|------------------------------|---------------|
| Sep-08-2020 10:17:07 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BNZPM4 | Initial Entry |
|--|-----------------|---------------------|------------------------------|---------------|

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1068

Subject No: 10681111

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-04-2020 17:03:11 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2. Treatment Name

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------------------|---------------|
| Sep-04-2020 17:03:11 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BLINDED THERAPY | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Sep-04-2020 17:03:11 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INJECTION | Initial Entry |

4. Dose Date Time:

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

| | | | | |
|--|-----------------|---------------------|--|---------------|
| Sep-04-2020 17:03:11 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/4/2020 16:34 | Initial Entry |
|--|-----------------|---------------------|--|---------------|

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------------------|---------------|
| Sep-04-2020 17:03:11 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------|---------------|
| Sep-04-2020 17:03:11 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: LEFT | Initial Entry |

7. Route:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Sep-04-2020 17:03:11 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1068

Subject No: 10681111

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Sep-04-2020 17:03:11 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N 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-04-2020 17:03:11 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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1. Select appropriate response - Reactogenicity diary collection

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Sep-04-2020 17:03:28 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO - REACTOGENI CITY E-DIARY NOT COLLECTED FOR T HIS SUBJECT | Initial Entry |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1068

Subject No: 10681111

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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1. Date of Visit

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Sep-25-2020 17:11:45 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/25/2020 | Initial Entry |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1068

Subject No: 10681111

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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1. Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Sep-25-2020 17:12:12 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/25/2020 | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Sep-25-2020 17:12:12 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier:: Temperature: 98.7 Temperature Unit: Temperature Location: ORAL CAVIT Y | Initial Entry |

2.a Record Identifier:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Sep-25-2020 17:12:12 (UTC-07:00) Mountain Time | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

(US & Canada)

2.a Temperature:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------|---------------|
| Sep-25-2020 17:12:12 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 98.7 | Initial Entry |

2.a Unit:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Sep-25-2020 17:12:12 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: F | Initial Entry |

2.a Temperature Location:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Sep-25-2020 17:12:12 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ORAL CAVITY | Initial Entry |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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1. Lab Panel:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Sep-25-2020 17:12:28 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2. Lab Sub-Panel:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Sep-25-2020 17:12:28 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Sep-25-2020 17:12:28 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

4. Laboratory Name and Address (Derived)

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

| | | | | |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Sep-25-2020 17:12:28 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |
|--|-----------------|---------------------|--------------------------------------|---------------|

5. Specimen Type:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Sep-25-2020 17:12:28 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

6.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Sep-25-2020 17:12:28 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Def Not Ap ined Identifi plicabl er: e Test:: Not Ap plicabl e Result:: Not Ap plicabl e Not Done:: Not Ap plicabl e | Initial Entry |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

6.a Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Sep-25-2020 17:12:28 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

6.a Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Sep-25-2020 17:12:28 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

6.a Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Sep-25-2020 17:12:28 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

6.a Not Done:

| Date | Location | User | Value | Reason |
|-------------------------|-----------------|---------------------|--------------------------------------|---------------|
| Sep-25-2020 17:12:28 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

(UTC-07:00)
Mountain Time
(US & Canada)

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

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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Sep-25-2020 17:12:45 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Sep-25-2020 17:12:45 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|-----------------|-------------------------------------|
| Sep-28-2020 11:39:32 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Sep-26-2020 03:44:07 (UTC-07:00) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | 'Sample Collected?' is Yes, however |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1068**Site Name:** (1068) Bozeman Health Clinical Research**Subject No:** 10681111**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:05

| | | | | |
|--|-----------------|---------------------------|---|--|
| Mountain Time (US & Canada) | | | | no barcodes are entered. Please review and correct as appropriate. |
| Sep-25-2020 17:12:45 (UTC-07:00) Mountain 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-25-2020 17:12:45 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Sep/25/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Sep-28-2020 11:39:32 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID BNZPT : 8 | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

| | | | | |
|--|-----------------|---------------------|------------------------------|---------------|
| Sep-28-2020 11:39:32 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BNZPT8 | Initial Entry |
|--|-----------------|---------------------|------------------------------|---------------|

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1068

Subject No: 10681111

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

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1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-25-2020 17:17:56 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2. Treatment Name

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------------------|---------------|
| Sep-25-2020 17:17:56 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BLINDED THERAPY | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Sep-25-2020 17:17:56 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INJECTION | Initial Entry |

4. Dose Date Time:

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

| | | | | |
|--|-----------------|---------------------|---|---------------|
| Sep-25-2020 17:17:56 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/25/2020 16:56 | Initial Entry |
|--|-----------------|---------------------|---|---------------|

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------------------|---------------|
| Sep-25-2020 17:17:56 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------|---------------|
| Sep-25-2020 17:17:56 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: LEFT | Initial Entry |

7. Route:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Sep-25-2020 17:17:56 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1068

Subject No: 10681111

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Sep-25-2020 17:17:56 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: THE PROTOCOL SPECIFIED OBSERVATION 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-25-2020 17:17:56 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (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: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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1. Date of Visit

| Date | Location | User | Value | Reason |
|--|-----------------|----------------------------|-------------------|---|
| Oct-31-2020 05:23:26 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Oct-30-2020 11:45:00 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | Emily Anglemyer (b) (4) | Query 1: Answered | Changed data per query |
| Oct-30-2020 02:55:53 (UTC-07:00) Mountain 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 |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (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: 1068 **Site Name:** (1068) Bozeman Health Clinical Research

Subject No: 10681111 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:05

| | | | | |
|--|-----------------|-------------------------------|-----------------------------------|---|
| | | | | EOT to match date of blood sample collection date at visit 3. |
| Oct-28-2020 07:46:16 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | Emily Anglemyer (b) (4) | Data Entry: Oct/27/2020 | Initial Entry |

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1068 **Site Name:** (1068) Bozeman Health Clinical Research

Subject No: 10681111 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:05

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Oct-28-2020 07:46:32 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Oct-28-2020 07:46:32 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------|-------------------------------------|
| Oct-28-2020 07:46:49 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Oct-28-2020 07:46:32 (UTC-07:00) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (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: 1068 Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 10:05

| | | | | |
|--|-----------------|-------------------------|---|--|
| Mountain Time (US & Canada) | | | | no barcodes are entered. Please review and correct as appropriate. |
| Oct-28-2020 07:46:32 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | Emily Anglemyer (b) (4) | Data Entry: YES Date of Collection: Oct/27/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Oct-28-2020 07:46:49 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | Emily Anglemyer (b) (4) | Data Entry: Sample I BNZP7 D: T | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|------------------------------|---------------|
| Oct-28-2020 07:46:49 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | Emily Anglemyer (b) (4) | Data Entry: BNZP7T | Initial Entry |

5.b

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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: 1068 **Site Name:** (1068) Bozeman Health Clinical Research

Subject No: 10681111 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:05

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------------|--|---------------|
| Oct-29-2020 13:20:08 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | Emily Anglemyer (b) (4) | Data Entry: Sample I BNVXJ D: G | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------------|------------------------------|---------------|
| Oct-29-2020 13:20:08 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | Emily Anglemyer (b) (4) | Data Entry: BNVXJG | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------------|--|---------------|
| Oct-29-2020 13:34:55 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | Emily Anglemyer (b) (4) | Data Entry: Sample I BNVXJ D: H | Initial Entry |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (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: 1068 **Site Name:** (1068) Bozeman Health Clinical Research

Subject No: 10681111 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:05

5.c Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------------|------------------------------|---------------|
| Oct-29-2020 13:34:55 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | Emily Anglemyer (b) (4) | Data Entry: BNVXJH | Initial Entry |

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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1. Date of Completion/Discontinuation/Death :

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------------|-----------------------------------|---------------|
| Oct-30-2020 11:44:41 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | Emily Anglemyer (b) (4) | Data Entry: Oct/27/2020 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-----------------------------------|---------------|
| Oct-30-2020 11:44:41 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: VACCINATION | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------------|---------------------------------|---------------|
| Oct-30-2020 11:44:41 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | Emily Anglemyer (b) (4) | Data Entry: COMPLETED | Initial Entry |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------|--------|
| Sep-18-2020 15:05:02 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------|--------|
| Sep-18-2020 15:06:36 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------|--------|
| Sep-18-2020 15:10:10 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------|--------|
| Sep-18-2020 15:12:03 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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1. Category:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Sep-18-2020 15:05:02 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------|---------------|
| Sep-18-2020 15:05:02 (UTC-07:00) Mountain 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 |
|--|-----------------|---------------------------|-------------------|--------------------------|
| Oct-21-2020 18:43:57 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | Response satisfies query |
| Oct-20-2020 17:15:59 (UTC-07:00) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Answered | Transcription Error |

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

| | | | | |
|--|-----------------|----------------------------|---|--|
| Mountain Time (US & Canada) | | | | |
| Oct-20-2020 17:15:59 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | Michaela ODonoghue (b) (4) | Data Entry: Swollen Cervical Lymph Nodes bilateral | Transcription Error |
| Oct-19-2020 23:23:21 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened | ClinQuery: Swollen Cervical Lymph Nodes: please Specify whether bilateral, left or right |
| Oct-19-2020 19:39:17 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Candidate | ClinQuery: Swollen Cervical Lymph Nodes: please Specify whether bilateral, left or right |
| Sep-23-2020 04:21:48 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | Juleen Gayed (b) (4) | Query 1: Closed | Response satisfies query |
| Sep-21-2020 12:18:29 (UTC-07:00) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | New Information |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1068**Site Name:** (1068) Bozeman Health Clinical Research**Subject No:** 10681111**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:05

| | | | | |
|--|-----------------|--------------------------------|--|---|
| Mountain Time (US & Canada) | | | | |
| Sep-21-2020 12:18:29 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: Swollen Cervical Lymph Nodes | New Information |
| Sep-21-2020 09:35:13 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | Juleen Gayed (b) (4) | Query 1: Opened | Clin: Please clarify site of the swollen lymph node |
| Sep-18-2020 15:05:02 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: Swollen Lymph Node | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------------|--|---------------|
| Sep-18-2020 15:05:02 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: Sep/5/2020 UNK:UNK | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

| | | | | |
|--|-----------------|---------------------|--|---------------|
| Sep-18-2020 15:05:02 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date Time: Sep/7/2020 UNK:U NK | Initial Entry |
|--|-----------------|---------------------|--|---------------|

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Sep-18-2020 15:05:02 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | 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 |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-18-2020 15:05:02 (UTC-07:00) Mountain 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?

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

If Yes, record the type of medication error on the Medication Error Log.

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Sep-18-2020 15:05:02 (UTC-07:00) Mountain 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 |
|--|-----------------|------------------|-------------------------------|---------------|
| Sep-18-2020 15:05:02 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RELATED | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------------------|---------------|
| Sep-18-2020 15:05:02 (UTC-07:00) Mountain 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 |
|-------------------------|-----------------|------------------|--------------------------|---------------|
| Sep-18-2020 15:05:02 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

(UTC-07:00)
Mountain Time
(US & Canada)

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-18-2020 15:05:02 (UTC-07:00) Mountain 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 |
|--|-----------------|-------------------------------|--|--|
| Sep-18-2020 15:11:23 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Sep-18-2020 15:11:23 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | Emily Anglemyer (b) (4) | Data Entry: RECOVERED/ RESOLVED | Transcription Error |
| Sep-18-2020 15:05:02 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | For AE Swollen Lymph Node: Response to "What was the outcome of this adverse event?" |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

| | | | | |
|--|-----------------|------------------|--|--|
| | | | | is 'Not Recovered/Not Resolved' but AE End Date/Time is present. |
| Sep-18-2020 15:05:02 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT RECOVERED/NOT RESOLVED | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Sep-18-2020 15:05:02 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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1. Category:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Sep-18-2020 15:06:36 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------|---------------|
| Sep-18-2020 15:06:36 (UTC-07:00) Mountain 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 |
|--|-----------------|---------------------|---|---------------|
| Sep-18-2020 15:06:36 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Injection Site Pain | Initial Entry |

4. Start Date Time:

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Sep-18-2020 15:06:36 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/5/2020 UNK:UN K | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Sep-18-2020 15:06:36 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date Time: Sep/7/2020 UNK:U NK | Initial Entry |

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Sep-18-2020 15:06:36 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | 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

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Sep-18-2020 15:06:36 (UTC-07:00) Mountain 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 |
|--|-----------------|------------------|--------------------------|---------------|
| Sep-18-2020 15:06:36 (UTC-07:00) Mountain 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 |
|--|-----------------|------------------|-------------------------------|---------------|
| Sep-18-2020 15:06:36 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RELATED | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

| | | | | |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Sep-18-2020 15:06:36 (UTC-07:00) Mountain 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 |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-18-2020 15:06:36 (UTC-07:00) Mountain 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 |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-18-2020 15:06:36 (UTC-07:00) Mountain 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 |
|--|-----------------|---------------------|--|---------------|
| Sep-18-2020 15:06:36 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RECOVERED/RESOLVED | Initial Entry |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-18-2020 15:06:36 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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1. Category:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Sep-18-2020 15:10:10 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------|---------------|
| Sep-18-2020 15:10:10 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 3 | Initial Entry |

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Sep-18-2020 15:10:10 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sneezing | Initial Entry |

4. Start Date Time:

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Sep-18-2020 15:10:10 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/5/2020 UNK:UN K | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Sep-18-2020 15:10:10 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date Time: Sep/7/2020 UNK:U NK | Initial Entry |

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Sep-18-2020 15:10:10 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | 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

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Sep-18-2020 15:10:10 (UTC-07:00) Mountain 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 |
|--|-----------------|------------------|--------------------------|---------------|
| Sep-18-2020 15:10:10 (UTC-07:00) Mountain 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 |
|--|-----------------|-------------------------|-------------------|---------------------------|
| Sep-23-2020 04:14:53 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | Juleen Gayed (b) (4) | Query 1: Closed | Response satisfies query |
| Sep-22-2020 13:18:23 (UTC-07:00) Mountain Time | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Original value is correct |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

| | | | | |
|--|-----------------|-------------------------|-------------------------------|---|
| (US & Canada) | | | | |
| Sep-21-2020 11:08:16 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | Juleen Gayed (b) (4) | Query 1: Opened | Clin: Please clarify causality in light of associated AE, is another cause plausible? |
| Sep-18-2020 15:10:10 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RELATED | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------------------|---------------|
| Sep-18-2020 15:10:10 (UTC-07:00) Mountain 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 |
|--|-----------------|------------------|--------------------------|---------------|
| Sep-18-2020 15:10:10 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-18-2020 15:10:10 (UTC-07:00) Mountain 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 |
|--|-----------------|---------------------|--|---------------|
| Sep-18-2020 15:10:10 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RECOVERED/RESOLVED | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-18-2020 15:10:10 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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1. Category:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Sep-18-2020 15:12:03 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------|---------------|
| Sep-18-2020 15:12:03 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 4 | Initial Entry |

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------------|-------------------|------------------------------|
| Sep-22-2020 21:37:13 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | Salim Bouguermouh (b) (4) | Query 1: Closed | Response satisfies query |
| Sep-21-2020 12:17:30 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Original value is correct |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001
Visit: Logs - Unscheduled **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1068 **Site Name:** (1068) Bozeman Health Clinical Research
Subject No: 10681111 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:05

| | | | | |
|--|-----------------|---------------------------------|----------------------------------|--|
| (UTC-07:00) Mountain Time (US & Canada) | | | | |
| Sep-21-2020 09:51:48 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | Salim Bouguermouh (b) (4) | Query 1: Opened | Clin: Since NASAL CONGESTION or RUNNY NOSE is one of the CDC-defined symptoms of COVID-19 (see protocol section 8.1), please consider whether this symptom could have been due to COVID-19 and should have triggered a potential illness visit. |
| Sep-18-2020 15:12:03 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Rhinorrhea | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

| | | | | |
|--|-----------------|---------------------|--|---------------|
| Sep-18-2020 15:12:03 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/5/2020 UNK:UN K | Initial Entry |
|--|-----------------|---------------------|--|---------------|

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Sep-18-2020 15:12:03 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date Time: Sep/7/2020 UNK:U NK | Initial Entry |

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Sep-18-2020 15:12:03 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | 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).

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Sep-18-2020 15:12:03 (UTC-07:00) Mountain 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 |
|--|-----------------|------------------|--------------------------|---------------|
| Sep-18-2020 15:12:03 (UTC-07:00) Mountain 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 |
|--|-----------------|-------------------------|-------------------|---------------------------|
| Sep-23-2020 04:13:43 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | Juleen Gayed (b) (4) | Query 1: Closed | Response satisfies query |
| Sep-21-2020 12:17:48 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Original value is correct |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

| | | | | |
|--|-----------------|-------------------------|-------------------------------|---|
| Sep-21-2020 11:08:56 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | Juleen Gayed (b) (4) | Query 1: Opened | Clin: Please clarify causality in light of associated AE, is another cause plausible? |
| Sep-18-2020 15:12:03 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RELATED | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------------------|---------------|
| Sep-18-2020 15:12:03 (UTC-07:00) Mountain 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 |
|--|-----------------|------------------|--------------------------|---------------|
| Sep-18-2020 15:12:03 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-18-2020 15:12:03 (UTC-07:00) Mountain 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 |
|--|-----------------|---------------------|--|---------------|
| Sep-18-2020 15:12:03 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RECOVERED/RESOLVED | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-18-2020 15:12:03 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History
Unscheduled

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1068 **Site Name:** (1068) Bozeman Health Clinical Research

Subject No: 10681111 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:05

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1. Date of Visit

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------------|-----------------------------------|---------------|
| Dec-18-2020 12:22:12 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | Emily Anglemyer (b) (4) | Data Entry: Dec/18/2020 | Initial Entry |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen, Verified

Site No: 1068 **Site Name:** (1068) Bozeman Health Clinical Research

Subject No: 10681111 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:05

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

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------------|---|--|
| Dec-18-2020 12:22:56 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Dec-18-2020 12:22:25 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candid ate | The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date. |
| Dec-18-2020 12:22:25 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | Emily Anglemyer (b) (4) | Data Entry: Participant is wil ling to return for Vaccination 3 Participant is: eligible and N OT confirmed to have receiv ed only place | Initial Entry |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen, Verified

Site No: 1068 **Site Name:** (1068) Bozeman Health Clinical Research

Subject No: 10681111 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:05

| | | | | |
|--|--|--|---------------------------|--|
| | | | bo at Vaccinat ion 1/2 | |
|--|--|--|---------------------------|--|

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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1. Date Treatment Unblinded :

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------------|-----------------------------------|---------------|
| Dec-18-2020 12:22:56 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | Emily Anglemyer (b) (4) | Data Entry: Dec/18/2020 | Initial Entry |

2. Primary Reason for Unblinding:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------------|---|---------------|
| Dec-18-2020 12:22:56 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | Emily Anglemyer (b) (4) | Data Entry: ASSESS ELIGIBI LITY FOR ADDIT IONAL VACCINA TION | Initial Entry |

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

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1. Subject Status

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Oct-30-2020 11:44:41 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: FOLLOW-UP | Initial Entry |
| Sep-04-2020 17:01:53 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ENROLLED/RANDOMIZED | Initial Entry |
| Sep-04-2020 16:59:14 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SCREENED | Initial Entry |

2. Subject Status Date

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-----------------------------------|---------------|
| Oct-30-2020 11:44:41 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Oct/27/2020 | Initial Entry |
| Sep-04-2020 17:01:53 | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sep/4/2020 | Initial Entry |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1068

Site Name: (1068) Bozeman Health Clinical Research

Subject No: 10681111

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:05

| | | | | |
|--|-----------------|-------------------------|----------------------------------|---------------|
| (UTC-07:00) Mountain Time (US & Canada) | | | | |
| Sep-04-2020 16:59:14 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sep/4/2020 | Initial Entry |

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1068

Subject No: 10681111

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1068) Bozeman Health Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:05

[Back to Form](#)

1. Casebook Signature

| Date | Location | User | Value | Reason |
|--|-----------------|-----------------------------|--|---------------|
| Nov-02-2020 18:28:03 (UTC-07:00) Mountain Time (US & Canada) | ACV0PFEINFP6000 | Andrew Gentry (b) (4) | Data Entry: Click Here to Enable | Initial Entry |

090177e196ae2fdc\Final\Final On: 01-Apr-2021 03:54 (GMT)