

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[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 | 08 SEP 2020 |
| 2. | Select appropriate response - What cohort does the subject belong to? | STAGE 3 COHORTS |

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Informed Consent

| | | |
|----|--------------|--|
| 1. | Consent Was: | OBTAINED Date Written Consent Obtained Sep/22/2020 |
|----|--------------|--|

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Demography

| | | |
|----|---------------------------------|--|
| 1. | Subject ID | [12641195] |
| 2. | Birth Date: | (b) (6)/1946 |
| 3. | Sex: | FEMALE |
| 4. | Ethnicity: | NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN |
| 5. | Race: (Check X all that apply): | BLACK OR AFRICAN AMERICAN |
| 6. | Racial Designation: | |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Disposition - Screening

| | | |
|----|--|-------------|
| 1. | Date of Completion/Discontinuation/Death | Sep/22/2020 |
| 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: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Medical History Details

| | | |
|-----|--|---|
| 1.a | Line/MH Number: | [1] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Eczema] |
| | Start Date: | Mar/UNK/2018 |
| | Ongoing: | YES |
| 1.b | Line/MH Number: | [2] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Asthma] |
| | Start Date: | UNK/UNK/1950 |
| | Ongoing: | YES |
| 1.c | Line/MH Number: | [3] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Meningioma (asymptomatic, stable, no treatment plans)] |
| | Start Date: | UNK/UNK/2015 |
| | Ongoing: | YES |
| 1.d | Line/MH Number: | [4] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Vitiligo] |
| | Start Date: | UNK/UNK/2016 |
| | Ongoing: | YES |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | |
|-----|--|---|
| 1.e | Line/MH Number: | [5] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | ["Pre-diabetes" elevated HgbA1C] |
| | Start Date: | UNK/UNK/2011 |
| | Ongoing: | YES |
| 1.f | Line/MH Number: | [6] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Latex allergy] |
| | Start Date: | UNK/UNK/2010 |
| | Ongoing: | YES |
| 1.g | Line/MH Number: | [7] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Sulfa allergy (hives)] |
| | Start Date: | UNK/UNK/1980 |
| | Ongoing: | YES |
| 1.h | Line/MH Number: | [8] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Seasonal allergies (molds and spores)] |
| | Start Date: | UNK/UNK/1950 |
| | Ongoing: | YES |
| 1.i | Line/MH Number: | [9] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Osteoarthritis] |
| | Start Date: | UNK/UNK/2010 |
| | Ongoing: | YES |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | |
|-----|--|--|
| 1.j | Line/MH Number: | [10] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Penicillin allergy (hives)] |
| | Start Date: | UNK/UNK/2000 |
| | Ongoing: | YES |
| 1.k | Line/MH Number: | [11] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Amoxicillin allergy (hives)] |
| | Start Date: | UNK/UNK/2000 |
| | Ongoing: | YES |
| 1.l | Line/MH Number: | [12] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Inner ear pain 14d post shingles vaccine] |
| | Start Date: | Nov/UNK/2015 |
| | Ongoing: | NO End Date: Dec/UNK/2015 |
| 1.m | Line/MH Number: | [13] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Tubal ligation] |
| | Start Date: | UNK/UNK/1974 |
| | Ongoing: | NO End Date: UNK/UNK/1974 |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | |
|-----|--|--|
| 1.n | Line/MH Number: | [14] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Skin biopsy (benign)] |
| | Start Date: | UNK/UNK/1985 |
| | Ongoing: | NO End Date: UNK/UNK/1985 |
| 1.o | Line/MH Number: | [15] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Breast biopsy (benign)] |
| | Start Date: | UNK/UNK/2018 |
| | Ongoing: | NO End Date: UNK/UNK/2018 |
| 1.p | Line/MH Number: | [16] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Prednisone taper] |
| | Start Date: | Nov/UNK/2015 |
| | Ongoing: | NO End Date: Dec/UNK/2015 |
| 1.q | Line/MH Number: | [17] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Acupuncture] |
| | Start Date: | Nov/UNK/2015 |
| | Ongoing: | NO End Date: Dec/UNK/2015 |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | |
|-----|--|--------------------------------------|
| 1 r | Line/MH Number: | [18] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Tinnitus 14d post shingles vaccine] |
| | Start Date: | Nov/UNK/2015 |
| | Ongoing: | NO End Date: Dec/UNK/2015 |
| 1.s | Line/MH Number: | [19] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Vertigo 14d post shingles vaccine] |
| | Start Date: | Nov/UNK/2015 |
| | Ongoing: | NO End Date: Dec/UNK/2015 |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: HIV STATUS

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

HIV Status

| | | |
|----|---|---|
| 1. | Select appropriate response - What is the subject HIV status? | The subject is NOT known to be HIV POSITIVE |
|----|---|---|

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

eCRF Audit Trail History

Vital Signs

| | | |
|----|------------------|-------------|
| 1. | Date: | Sep/22/2020 |
| 2. | Weight: | [102.2] |
| 3. | Unit: | kg |
| 4. | Height: | [167.5] |
| 5. | Unit: | cm |
| 6. | Body Mass Index: | [36.4] |

Vital Signs Details

| | | |
|-----|-----------------------|----------|
| 7.a | Record Identifier: | 1 |
| | Temperature: | [36.3] |
| | Unit: | C |
| | Temperature Location: | FOREHEAD |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:51

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

eCRF Audit Trail History

Lab Urinalysis

| | | |
|----|---------------------------------------|--------------|
| 1. | Lab Panel: | URINALYSIS |
| 2. | Lab Sub-Panel: | PREGNANCY |
| 3. | Collection Date: | Sep/22/2020 |
| 4. | Laboratory Name and Address (Derived) | [STUDY SITE] |
| 5. | Specimen Type: | URINE |

Lab Result

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

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Disposition

| | | |
|----|-----------------------|-------------|
| 1. | Randomization Date : | Sep/22/2020 |
| 2. | Randomization Number: | [264013] |
| 3. | Randomization Group: | [] |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

eCRF Audit Trail History

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Sep/22/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BM92PN] |
| 5.b | Sample ID | [BNWC66] |
| 5.c | Sample ID | [BNWC67] |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

eCRF Audit Trail History

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Sep/22/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BM92PJ] |
|-----|-----------|----------|

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

eCRF Audit Trail History

Vaccination

| | | |
|-----|---|---|
| 1. | Was there a temporary delay of vaccination? | NO |
| 2. | Treatment Name | [BLINDED THERAPY] |
| 3. | Formulation: | INJECTION |
| 4. | Dose Date Time: | Sep/22/2020 14:50 |
| 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 |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Oct/14/2020 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Vital Signs

| | | |
|----|-------|-------------|
| 1. | Date: | Oct/14/2020 |
|----|-------|-------------|

Vital Signs Details

| | | |
|-----|-----------------------|----------|
| 2.a | Record Identifier: | 1 |
| | Temperature: | [36.2] |
| | Unit: | C |
| | Temperature Location: | FOREHEAD |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:51

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

eCRF Audit Trail History

Lab Urinalysis

| | | |
|----|---------------------------------------|--------------|
| 1. | Lab Panel: | URINALYSIS |
| 2. | Lab Sub-Panel: | PREGNANCY |
| 3. | Collection Date: | Oct/14/2020 |
| 4. | Laboratory Name and Address (Derived) | [STUDY SITE] |
| 5. | Specimen Type: | URINE |

Lab Result

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

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

eCRF Audit Trail History

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Oct/14/2020 |
| 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 | [BM92W6] |
|-----|-----------|----------|

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

eCRF Audit Trail History

Vaccination

| | | | |
|-----|---|--|--------------------------|
| 1. | Was there a temporary delay of vaccination? | YES Date of First Delay: Oct/14/2020 Reason(s) for Temporary Delay of Vaccination FEVER OR ACUTE ILLNESS | |
| 2. | Treatment Name | [] | |
| 3. | Formulation: | | |
| 4. | Dose Date Time: | Not Applicable _____ // | Comments |
| 5. | Anatomical Location: | | |
| 6. | Body Side: | Not Applicable _____ | Comments |
| 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? | Not Applicable _____ | Comments |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Nov/13/2020 |
| 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: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

eCRF Audit Trail History

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Nov/13/2020 |
| 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 | [BM92D6] |
| 5.b | Sample ID | [BRSSHW] |
| 5.c | Sample ID | [BRSSHX] |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (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: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Date of Visit

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

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

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: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

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: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

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: 1264 **Site Name:** (1264) University of California Davis Health

Subject No: 12641195 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

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: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Feb/24/2021

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Feb/24/2021 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/24/2021

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Unplanned Assessments

| | | |
|----|-------------|-----------------|
| 1. | Assessments | CONTACT OUTCOME |
|----|-------------|-----------------|

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/24/2021

Form: CONTACT OUTCOME - UNPLANNED

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Contact Outcome

| | | |
|----|-------------------|--|
| 1. | Contact Type: | TELEPHONE VISIT |
| 2. | Was contact made? | YES Date of Contact: Feb/24/2021 Contact Outcome: VISIT ARRANGED |
| 3. | Comments: | [] |

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Feb/24/2021

Form: VITAL SIGNS - TEMP

Form Version: 20-Feb-2021 02:16

Form Status: Data Complete, Frozen, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Vital Signs

| | | |
|----|-------|-------------|
| 1. | Date: | Feb/24/2021 |
|----|-------|-------------|

Vital Signs Details

| | | |
|-----|-----------------------|----------|
| 2.a | Record Identifier: | 1 |
| | Temperature: | [36.5] |
| | Unit: | C |
| | Temperature Location: | FOREHEAD |

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/24/2021

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT

Form Version: 20-Feb-2021 02:13

Form Status: Data Complete, Frozen, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Unplanned Assessment Of Local Reaction

| | | |
|----|---------------------------|----------------|
| 1. | Date of Assessment: | Feb/24/2021 |
| 2. | Injection Site Location | DELTOID MUSCLE |
| 3. | Injection Site Body Side: | LEFT |

Reaction

| | | |
|-----|-------------------|----------|
| 4.a | Reaction: | REDNESS |
| | Reaction Present: | NO |
| 4.b | Reaction: | SWELLING |
| | Reaction Present: | NO |

Symptom

| | | |
|-----|------------------|-------------------------------|
| 5.a | Symptom: | PAIN AT INJECTION SITE |
| | Symptom Present: | NO |
| 5.b | Symptom: | FATIGUE/TIREDNESS |
| | Symptom Present: | NO |
| 5.c | Symptom: | HEADACHE |
| | Symptom Present: | NO |
| 5.d | Symptom: | VOMITING |
| | Symptom Present: | NO |
| 5.e | Symptom: | DIARRHEA |
| | Symptom Present: | NO |
| 5.f | Symptom: | NEW OR WORSENERED MUSCLE PAIN |
| | Symptom Present: | NO |

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Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/24/2021

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT

Form Version: 20-Feb-2021 02:13

Form Status: Data Complete, Frozen, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

| | | |
|-----|------------------|-----------------------------|
| 5.g | Symptom: | NEW OR WORSENERD JOINT PAIN |
| | Symptom Present: | NO |
| 5 h | Symptom: | CHILLS |
| | Symptom Present: | NO |

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

| # | Category | AE Identifier | Adverse Event | Start Date | Is the Adverse Event Still Ongoing | Form Instance |
|----|---------------|---------------|------------------------------|--------------------|---|---------------------------------|
| 1. | ADVERSE EVENT | 1 | Cheilitis | Oct/7/2020 UNK:UNK | NO End Date Time: Nov/9/2020 UNK:UNK | Repeating Pages |
| 2. | ADVERSE EVENT | 2 | Dry mouth | Oct/7/2020 UNK:UNK | YES | Repeating Pages |
| 3. | ADVERSE EVENT | 3 | Pruritus, abdomen | Oct/7/2020 UNK:UNK | YES | Repeating Pages |
| 4. | ADVERSE EVENT | 4 | Rash maculo-papular, abdomen | Oct/7/2020 UNK:UNK | YES | Repeating Pages |
| 5. | ADVERSE EVENT | 5 | Hyperosmia | Oct/7/2020 UNK:UNK | NO End Date Time: Nov/13/2020 UNK:UNK | Repeating Pages |
| 6. | ADVERSE EVENT | 6 | Worsening eczema | Oct/7/2020 UNK:UNK | YES | Repeating Pages |
| 7. | ADVERSE EVENT | 7 | Dysgeusia | Oct/7/2020 UNK:UNK | NO End Date Time: Nov/13/2020 UNK:UNK | Repeating Pages |

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1264) University of California Davis Health

Subject Initials: ---

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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) | [Cheilitis] |
| 4. | Start Date Time: | Oct/7/2020 UNK:UNK |
| 5. | Is the adverse event still ongoing? | NO End Date Time: Nov/9/2020 UNK:UNK |
| 6. | Toxicity Grade: | 2 |
| 7. | Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). | NO |
| 8. | Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log. | NO |
| 9. | Is this event related to study treatment: | RELATED |
| 10. | Latest Action Taken with Study Treatment: | NOT APPLICABLE |
| 11. | Was a Concomitant Medication given? | YES |

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Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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

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Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1264) University of California Davis Health

Subject Initials: ---

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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) | [Dry mouth] |
| 4. | Start Date Time: | Oct/7/2020 UNK:UNK |
| 5. | Is the adverse event still ongoing? | YES |
| 6. | Toxicity Grade: | 2 |
| 7. | Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). | NO |
| 8. | Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log. | NO |
| 9. | Is this event related to study treatment: | RELATED |
| 10. | Latest Action Taken with Study Treatment: | DRUG WITHDRAWN |
| 11. | Was a Concomitant Medication given? | NO |

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | |
|-----|--|----------------------------|
| 12. | Was a Non-Drug Treatment given? | NO |
| 13. | What was the outcome of this adverse event?: | NOT RECOVERED/NOT 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

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Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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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) | [Pruritus, abdomen] |
| 4. | Start Date Time: | Oct/7/2020 UNK:UNK |
| 5. | Is the adverse event still ongoing? | YES |
| 6. | Toxicity Grade: | 2 |
| 7. | Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). | NO |
| 8. | Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log. | NO |
| 9. | Is this event related to study treatment: | RELATED |
| 10. | Latest Action Taken with Study Treatment: | DRUG WITHDRAWN |
| 11. | Was a Concomitant Medication given? | NO |

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | |
|-----|--|----------------------------|
| 12. | Was a Non-Drug Treatment given? | YES |
| 13. | What was the outcome of this adverse event?: | NOT RECOVERED/NOT 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: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1264) University of California Davis Health

Subject Initials: ---

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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) | [Rash maculo-papular, abdomen] |
| 4. | Start Date Time: | Oct/7/2020 UNK:UNK |
| 5. | Is the adverse event still ongoing? | YES |
| 6. | Toxicity Grade: | 1 |
| 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: | DRUG WITHDRAWN |
| 11. | Was a Concomitant Medication given? | NO |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | |
|-----|--|----------------------------|
| 12. | Was a Non-Drug Treatment given? | YES |
| 13. | What was the outcome of this adverse event?: | NOT RECOVERED/NOT 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

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Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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Adverse Event Report

| | | |
|-----|---|---|
| 1. | Category: | ADVERSE EVENT |
| 2. | AE ID: | [5] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [Hyperosmia] |
| 4. | Start Date Time: | Oct/7/2020 UNK:UNK |
| 5. | Is the adverse event still ongoing? | NO End Date Time: Nov/13/2020 UNK:UNK |
| 6. | Toxicity Grade: | 1 |
| 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 |

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | |
|-----|--|--------------------|
| 11. | Was a Concomitant Medication given? | NO |
| 12. | Was a Non-Drug Treatment given? | NO |
| 13. | What was the outcome of this adverse event?: | RECOVERED/RESOLVED |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | NO |
| 15. | Serious Adverse Event Number: For Pfizer Use Only | [] |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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Adverse Event Report

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

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | |
|-----|--|----------------------------|
| 12. | Was a Non-Drug Treatment given? | NO |
| 13. | What was the outcome of this adverse event?: | NOT RECOVERED/NOT 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 | [] |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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Adverse Event Report

| | | |
|-----|---|---|
| 1. | Category: | ADVERSE EVENT |
| 2. | AE ID: | [7] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [Dysgeusia] |
| 4. | Start Date Time: | Oct/7/2020 UNK:UNK |
| 5. | Is the adverse event still ongoing? | NO End Date Time: Nov/13/2020 UNK:UNK |
| 6. | Toxicity Grade: | 1 |
| 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 |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | |
|-----|--|--------------------|
| 11. | Was a Concomitant Medication given? | NO |
| 12. | Was a Non-Drug Treatment given? | NO |
| 13. | What was the outcome of this adverse event?: | RECOVERED/RESOLVED |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | NO |
| 15. | Serious Adverse Event Number: For Pfizer Use Only | [] |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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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 | [] |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

| # | 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: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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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: | // |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

| # | 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 Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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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? | |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Disposition - Treatment

| | | |
|----|--|---------------|
| 1. | Date of Completion/Discontinuation/Death : | Oct/14/2020 |
| 2. | Phase of Disposition: | VACCINATION |
| 3. | Status: | ADVERSE EVENT |
| 4. | Specify Status: | [] |

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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: | |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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? | |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Contact Outcome

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

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Disposition - Follow-Up

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Jan/30/2021 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[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 per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2 |
|----|---|---|

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Treatment Unblinded

| | | |
|----|--------------------------------|---|
| 1. | Date Treatment Unblinded : | Jan/30/2021 |
| 2. | Primary Reason for Unblinding: | ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION |

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Withdrawal Of Consent

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

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|------------|
| 1. | Date of Visit | Mar/3/2021 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

| | | |
|----|--------------|---|
| 1. | Consent Was: | OBTAINED Date Written Consent Obtained Mar/3/2021 |
|----|--------------|---|

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Not Started

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Inclusion Criteria Not Met

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

Exclusion Criteria Met

| | | |
|----|--|--|
| 2. | Description of Exclusion Criterion Met | |
|----|--|--|

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

| | | |
|----|--|--------------------|
| 1. | Date of Completion/Discontinuation/Death : | Mar/3/2021 |
| 2. | Phase of Disposition: | REPEAT SCREENING 1 |
| 3. | Status: | COMPLETED |
| 4. | Specify Status: | [] |

Header Text: c4591001

Visit: V101_VAX3

Form Version: 20-Feb-2021 02:14

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

eCRF Audit Trail History

Lab Urinalysis

| | | |
|----|---------------------------------------|--------------|
| 1. | Lab Panel: | URINALYSIS |
| 2. | Lab Sub-Panel: | PREGNANCY |
| 3. | Collection Date: | Mar/3/2021 |
| 4. | Laboratory Name and Address (Derived) | [STUDY SITE] |
| 5. | Specimen Type: | URINE |

Lab Result

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

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

eCRF Audit Trail History

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Feb/24/2021 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BR4FBV] |
| 5.b | Sample ID | [BSGR87] |
| 5.c | Sample ID | [BSGR88] |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

eCRF Audit Trail History

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Feb/24/2021 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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

Vaccination

| | | | |
|-----|---|------------------|--------------------------|
| 1. | Was there a temporary delay of vaccination? | NO | Comments |
| 2. | Treatment Name | [BNT162b2] | Comments |
| 3. | Formulation: | INJECTION | Comments |
| 4. | Dose Date Time: | Mar/3/2021 10:14 | Comments |
| 5. | Anatomical Location: | DELTOID MUSCLE | Comments |
| 6. | Body Side: | LEFT | Comments |
| 7. | Route: | INTRAMUSCULAR | Comments |
| 8. | Actual Dose: | [30.0] | Comments |
| 9. | Unit: | ug | Comments |
| 10. | Timeframe Subject Was Observed | 30 MINUTES | Comments |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? | YES | Comments |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Date of Visit

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

Header Text: c4591001

Visit: V102_VAX4

Form Version: 20-Feb-2021 02:14

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Not Started

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Lab Urinalysis

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

Lab Result

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

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Not Started

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: VACCINATION

Form Status: Not Started

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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? | |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Date of Visit

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

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Contact Outcome

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

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Date of Visit

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

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Contact Outcome

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

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Date of Visit

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

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Contact Outcome

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

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Not Started

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Disposition - Treatment

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Subject Status

| | | |
|----|---------------------|--------------|
| 1. | Subject Status | DISCONTINUED |
| 2. | Subject Status Date | Oct/14/2020 |

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: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[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: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[Audit Trail](#)

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

- CRF_Sign

| Name | Signature Meaning | Date | Type | Action |
|-------------------|-------------------|---|------|--------|
| Timothy Albertson | Approved | Mar-11-2021 14:42:59 (UTC-08:00) Pacific Time (US & Canada) | BOOK | Signed |

Affidavit:

By my dated signature below, I, TimothyAlbertson, 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 Version: 15-Sep-2020 21:53

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| Form | Sep-23-2020 13:39:30 (UTC-08:00) Pacific Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---|----------------|
| 4 | Oct-16-2020 08:43:41 (UTC-08:00) Pacific Time (US & Canada) | (b) (4), (b) (6) [Redacted] [Redacted] | Not Applicable |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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| Item | Date | User | Comment |
|------|---|---|----------------|
| 6 | Oct-16-2020 08:43:49 (UTC-08:00) Pacific Time (US & Canada) | (b) (4), (b) (6) [Redacted] [Redacted] | Not Applicable |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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| Item | Date | User | Comment |
|------|---|---|----------------|
| 11 | Oct-16-2020 08:43:56 (UTC-08:00) Pacific Time (US & Canada) | (b) (4), (b) (6) [Redacted] [Redacted] | Not Applicable |

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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| Item | Date | User | Comment |
|------|---|------------------|---|
| Form | Mar-10-2021 13:23:37 (UTC-08:00) Pacific Time (US & Canada) | (b) (4), (b) (6) | Please unfreeze V101VAX3 VACCINE TRT because I need to enter data. It is not allowing me to change the data. |
| Form | Mar-08-2021 13:58:04 (UTC-08:00) Pacific Time (US & Canada) | (b) (4), (b) (6) | Please unfreeze V101VAX3 VACCINE TRT because I need to enter data. It is not allowing me to change the data. |
| Form | Mar-08-2021 11:49:19 (UTC-08:00) Pacific Time (US & Canada) | (b) (4), (b) (6) | Please unfreeze V101VAX3 VACCINE TRT because there was a transcription error. Thank you! |
| Form | Mar-03-2021 12:28:32 (UTC-08:00) Pacific Time (US & Canada) | (b) (4), (b) (6) | Please unfreeze V101VAX3 because there was a transcription error. Thank you! |
| Form | Feb-24-2021 15:52:10 (UTC-08:00) Pacific Time (US & Canada) | (b) (4), (b) (6) | Subject was eligible for vaccination at V101 but because of a presumed reaction to her V1 dose, she was not dosed for V2 therefor drug was unable to be dispensed for V101 with an incomplete V2. Subject is rescheduled for Vaccination on 26February2021. <hr/> Not Done |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|---|
| 1 | Mar-10-2021 13:23:37 (UTC-08:00) Pacific Time (US & Canada) | (b) (4), (b) (6) | Please unfreeze V101VAX3 VACCINE TRT because I need to enter data. It is not allowing me to change the data. |
| 1 | Feb-24-2021 15:52:10 (UTC-08:00) Pacific Time (US & Canada) | (b) (4), (b) (6) | Subject was eligible for vaccination at V101 but because of a presumed reaction to her V1 dose, she was not dosed for V2 therefor drug was unable to be dispensed for V101 with an incomplete V2. Subject is rescheduled for Vaccination on 26February2021. <hr/> Not Done |

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|---|
| 2 | Mar-10-2021 13:23:37 (UTC-08:00) Pacific Time (US & Canada) | (b) (4), (b) (6) | Please unfreeze V101VAX3 VACCINE TRT because I need to enter data. It is not allowing me to change the data. |
| 2 | Feb-24-2021 15:52:10 (UTC-08:00) Pacific Time (US & Canada) | (b) (4), (b) (6) | Subject was eligible for vaccination at V101 but because of a presumed reaction to her V1 dose, she was not dosed for V2 therefor drug was unable to be dispensed for V101 with an incomplete V2. Subject is rescheduled for Vaccination on 26February2021. <hr/> Not Done |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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| Item | Date | User | Comment |
|------|---|------------------|---|
| 3 | Mar-10-2021 13:23:37 (UTC-08:00) Pacific Time (US & Canada) | (b) (4), (b) (6) | Please unfreeze V101VAX3 VACCINE TRT because I need to enter data. It is not allowing me to change the data. |
| 3 | Feb-24-2021 15:52:10 (UTC-08:00) Pacific Time (US & Canada) | (b) (4), (b) (6) | Subject was eligible for vaccination at V101 but because of a presumed reaction to her V1 dose, she was not dosed for V2 therefor drug was unable to be dispensed for V101 with an incomplete V2. Subject is rescheduled for Vaccination on 26February2021. <hr/> Not Done |

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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| Item | Date | User | Comment |
|------|---|------------------|---|
| 4 | Mar-10-2021 13:23:37 (UTC-08:00) Pacific Time (US & Canada) | (b) (4), (b) (6) | Please unfreeze V101VAX3 VACCINE TRT because I need to enter data. It is not allowing me to change the data. |
| 4 | Feb-24-2021 15:52:10 (UTC-08:00) Pacific Time (US & Canada) | (b) (4), (b) (6) | Subject was eligible for vaccination at V101 but because of a presumed reaction to her V1 dose, she was not dosed for V2 therefor drug was unable to be dispensed for V101 with an incomplete V2. Subject is rescheduled for Vaccination on 26February2021. <hr/> Not Done |

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|---|
| 5 | Mar-10-2021 13:23:37 (UTC-08:00) Pacific Time (US & Canada) | (b) (4), (b) (6) | Please unfreeze V101VAX3 VACCINE TRT because I need to enter data. It is not allowing me to change the data. |
| 5 | Feb-24-2021 15:52:10 (UTC-08:00) Pacific Time (US & Canada) | (b) (4), (b) (6) | Subject was eligible for vaccination at V101 but because of a presumed reaction to her V1 dose, she was not dosed for V2 therefor drug was unable to be dispensed for V101 with an incomplete V2. Subject is rescheduled for Vaccination on 26February2021. <hr/> Not Done |

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|---|
| 6 | Mar-10-2021 13:23:37 (UTC-08:00) Pacific Time (US & Canada) | (b) (4), (b) (6) | Please unfreeze V101VAX3 VACCINE TRT because I need to enter data. It is not allowing me to change the data. |
| 6 | Feb-24-2021 15:52:10 (UTC-08:00) Pacific Time (US & Canada) | (b) (4), (b) (6) | Subject was eligible for vaccination at V101 but because of a presumed reaction to her V1 dose, she was not dosed for V2 therefor drug was unable to be dispensed for V101 with an incomplete V2. Subject is rescheduled for Vaccination on 26February2021. <hr/> Not Done |

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|---|
| 7 | Mar-10-2021 13:23:37 (UTC-08:00) Pacific Time (US & Canada) | (b) (4), (b) (6) | Please unfreeze V101VAX3 VACCINE TRT because I need to enter data. It is not allowing me to change the data. |
| 7 | Feb-24-2021 15:52:10 (UTC-08:00) Pacific Time (US & Canada) | (b) (4), (b) (6) | Subject was eligible for vaccination at V101 but because of a presumed reaction to her V1 dose, she was not dosed for V2 therefor drug was unable to be dispensed for V101 with an incomplete V2. Subject is rescheduled for Vaccination on 26February2021. <hr/> Not Done |

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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| Item | Date | User | Comment |
|------|---|------------------|---|
| 8 | Mar-10-2021 13:23:37 (UTC-08:00) Pacific Time (US & Canada) | (b) (4), (b) (6) | Please unfreeze V101VAX3 VACCINE TRT because I need to enter data. It is not allowing me to change the data. |
| 8 | Feb-24-2021 15:52:10 (UTC-08:00) Pacific Time (US & Canada) | (b) (4), (b) (6) | Subject was eligible for vaccination at V101 but because of a presumed reaction to her V1 dose, she was not dosed for V2 therefor drug was unable to be dispensed for V101 with an incomplete V2. Subject is rescheduled for Vaccination on 26February2021. <hr/> Not Done |

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|---|
| 9 | Mar-10-2021 13:23:37 (UTC-08:00) Pacific Time (US & Canada) | (b) (4), (b) (6) | Please unfreeze V101VAX3 VACCINE TRT because I need to enter data. It is not allowing me to change the data. |
| 9 | Feb-24-2021 15:52:10 (UTC-08:00) Pacific Time (US & Canada) | (b) (4), (b) (6) | Subject was eligible for vaccination at V101 but because of a presumed reaction to her V1 dose, she was not dosed for V2 therefor drug was unable to be dispensed for V101 with an incomplete V2. Subject is rescheduled for Vaccination on 26February2021. <hr/> Not Done |

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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| Item | Date | User | Comment |
|------|---|------------------|---|
| 10 | Mar-10-2021 13:23:37 (UTC-08:00) Pacific Time (US & Canada) | (b) (4), (b) (6) | Please unfreeze V101VAX3 VACCINE TRT because I need to enter data. It is not allowing me to change the data. |
| 10 | Feb-24-2021 15:52:10 (UTC-08:00) Pacific Time (US & Canada) | (b) (4), (b) (6) | Subject was eligible for vaccination at V101 but because of a presumed reaction to her V1 dose, she was not dosed for V2 therefor drug was unable to be dispensed for V101 with an incomplete V2. Subject is rescheduled for Vaccination on 26February2021. <hr/> Not Done |

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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| Item | Date | User | Comment |
|------|---|------------------|---|
| 11 | Mar-10-2021 13:23:37 (UTC-08:00) Pacific Time (US & Canada) | (b) (4), (b) (6) | Please unfreeze V101VAX3 VACCINE TRT because I need to enter data. It is not allowing me to change the data. |
| 11 | Feb-24-2021 15:52:10 (UTC-08:00) Pacific Time (US & Canada) | (b) (4), (b) (6) | Subject was eligible for vaccination at V101 but because of a presumed reaction to her V1 dose, she was not dosed for V2 therefor drug was unable to be dispensed for V101 with an incomplete V2. Subject is rescheduled for Vaccination on 26February2021. <hr/> Not Done |

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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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 |
|-------------------|-------------------|---|------|--------|
| Timothy Albertson | Approved | Mar-11-2021 14:42:59 (UTC-08:00) Pacific Time (US & Canada) | BOOK | Signed |

Affidavit:

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

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

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

| | | | | |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Feb-09-2021 12:46:40 (UTC-08:00) Pacific Time (US & Canada) | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|-------------------|----------|---|------|--------|
| Timothy Albertson | Approved | Jan-22-2021 16:30:25 (UTC-08:00) Pacific Time (US & Canada) | BOOK | Signed |
|-------------------|----------|---|------|--------|

Affidavit:

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

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

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

| | | | | |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Dec-03-2020 09:45:17 (UTC-08:00) Pacific Time (US & Canada) | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:

N/A

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|-------------------|----------|---|------|--------|
| Timothy Albertson | Approved | Nov-16-2020 18:03:57 (UTC-08:00) Pacific Time (US & Canada) | BOOK | Signed |
|-------------------|----------|---|------|--------|

Affidavit:

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

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

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

| | | | | |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Nov-13-2020 14:26:15 (UTC-08:00) Pacific Time (US & Canada) | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|-------------------|----------|---|------|--------|
| Timothy Albertson | Approved | Nov-13-2020 14:07:59 (UTC-08:00) Pacific Time (US & Canada) | BOOK | Signed |
|-------------------|----------|---|------|--------|

Affidavit:

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

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

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

| | | | | |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Nov-13-2020 09:45:57 (UTC-08:00) Pacific Time (US & Canada) | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|-------------------|----------|---|------|--------|
| Timothy Albertson | Approved | Nov-11-2020 15:59:40 (UTC-08:00) Pacific Time (US & Canada) | BOOK | Signed |
|-------------------|----------|---|------|--------|

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Affidavit:

By my dated signature below, I, TimothyAlbertson, 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: COHORT_SELECTION

Form Version: 15-Sep-2020 21:55

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: COHORT SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Select appropriate response - Protocol version

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-23-2020 13:36:49 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 08 SEP 2020 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------------------|---------------|
| Sep-23-2020 13:36:49 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: STAGE 3 COHORTS | Initial Entry |

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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I. Consent Was:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-23-2020 13:37:16 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: OBTAINED Date Written Consent Obtained Sep/22/2020 | Initial Entry |

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Subject ID

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------|-----------------------------------|
| Sep-23-2020 13:36:41 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 12641195 | Item copied from previous form |

2. Birth Date:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|------------------------------------|------------------|
| Sep-23-2020 13:36:37 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: (b) (6)/1946 | Enrollment Entry |

3. Sex:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Sep-23-2020 13:39:06 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: FEMALE | Initial Entry |

4. Ethnicity:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-23-2020 13:39:06 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-23-2020 13:39:06 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BLACK OR AFRICAN AMERI CAN | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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I. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|-----------------------------------|---|
| Sep-25-2020 09:12:07 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Sep-25-2020 08:51:32 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Changed data per query |
| Sep-24-2020 13:36:08 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | ClinQuery: Please update Randomization page |
| Sep-23-2020 13:39:18 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/22/2020 | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date of Completion/Discontinuation/Death

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-23-2020 13:40:07 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/22/2020 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Sep-23-2020 13:40:07 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SCREENING | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------------|---------------|
| Sep-23-2020 13:40:07 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1.a

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Sep-23-2020 13:40:33 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 1 Medical History Term: Eczema Start Date: Mar/UNK/2018 Ongoing: YES | Initial Entry |

1.a Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-23-2020 13:40:33 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 1 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Sep-23-2020 13:40:33 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Eczema | Initial Entry |

1.a Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------------|---------------|
| Sep-23-2020 13:40:33 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Mar/UNK/2018 | Initial Entry |

1.a Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---------------------------|---------------|
| Sep-23-2020 13:40:33 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

I.b

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Sep-23-2020 13:40:53 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number 2 : Medical History Term: Start Date: UNK/UNK/1 950 Ongoing: YES | Initial Entry |

I.b Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-23-2020 13:40:53 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 2 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Sep-23-2020 13:40:53 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Asthma | Initial Entry |

I.b Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Sep-23-2020 13:40:53 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/1950 | Initial Entry |

I.b Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Sep-23-2020 13:40:53 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

I.c

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Sep-23-2020 13:41:29 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH 3 Number: Medical History Term: Meningioma (asymptomatic, stable, no treatment plans) Start Date: UNK/UNK/2015 e: Ongoing: YES | Initial Entry |

I.c Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-23-2020 13:41:29 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 3 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Sep-23-2020 13:41:29 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Meningioma (asymptomatic, stable, no treatment plans) | Initial Entry |

I.c Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------------|---------------|
| Sep-23-2020 13:41:29 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/2015 | Initial Entry |

I.c Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---------------------------|---------------|
| Sep-23-2020 13:41:29 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

I.d

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

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|---|-----------------|-------------------------|---|---------------|
| Sep-23-2020 13:41:42 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number 4 : Medical History Term: Vitiligo Start Date: UNK/UNK/2016 Ongoing: YES | Initial Entry |
|---|-----------------|-------------------------|---|---------------|

1.d Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-23-2020 13:41:42 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 4 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Sep-23-2020 13:41:42 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Vitiligo | Initial Entry |

1.d Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------------|---------------|
| Sep-23-2020 13:41:42 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/2016 | Initial Entry |

1.d Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---------------------------|---------------|
| Sep-23-2020 13:41:42 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

1.e

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------|---------------|
| Sep-23-2020 13:42:17 (UTC-08:00) Pacific | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|--------------------|--|--|--|--|
| Time (US & Canada) | | | Line/MH Number: 5 | |
| | | | Medical History Term: "Pre-diabetes" elevated HgbA1C | |
| | | | Start Date: UNK/UNK/2011 | |
| | | | Ongoing: YES | |

I.e Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------|-------------------------|---------------|
| Sep-23-2020 13:42:17 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 5 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Sep-23-2020 13:42:17 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> "Pre-diabetes" elevated HgbA1C | Initial Entry |

I.e Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------------|---------------|
| Sep-23-2020 13:42:17 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> UNK/UNK/2011 | Initial Entry |

I.e Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---------------------------|---------------|
| Sep-23-2020 13:42:17 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> YES | Initial Entry |

I.f

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------------|
| Sep-24-2020 09:52:03 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Line/MH Number: 6 | Transcription Error |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|---|-----------------|----------------------|--|---------------|
| | | | Medical History Term: Latex allergy Start Date: UNK/UNK/2010 Ongoing: YES | |
| Sep-23-2020 13:42:40 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 6 Medical History Term: Latex allergy (welts, rash) Start Date: UNK/UNK/2010 Ongoing: YES | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

1.f Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-23-2020 13:42:40 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 6 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|---|-----------------------------|-------------------------------------|--|
| Sep-24-2020 13:46:09 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 1: Clos ed | Discrepancy has been closed. |
| Sep-24-2020 09:52:03 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Ans wered | Transcription Error |
| Sep-24-2020 09:52:03 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Latex allergy | Transcription Error |
| Sep-23-2020 20:01:33 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 1: Ope ned | Multiple concepts in the term LATEX ALLERGY (WELTS, RASH). Split the term into LATEX ALLERGY and ALLERGIC WELTS, RASH and submit separately. Thank you. |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|---|-----------------|---------------------|---|---------------|
| Sep-23-2020 13:42:40 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Latex allergy (welts, rash) | Initial Entry |
|---|-----------------|---------------------|---|---------------|

I.f Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Sep-23-2020 13:42:40 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/2010 | Initial Entry |

I.f Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Sep-23-2020 13:42:40 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

I.g

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Sep-23-2020 13:42:56 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 7 r: Medical History Sulfa allergy (hives) Term: Start Date: UNK/UNK/1980 Ongoing: YES | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

I.g Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-23-2020 13:42:56 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 7 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-23-2020 13:42:56 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sulfa allergy (hives) | Initial Entry |

I.g Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Sep-23-2020 13:42:56 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/1980 | Initial Entry |

I.g Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Sep-23-2020 13:42:56 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

I.h

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Sep-23-2020 13:43:23 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH N umber: 8 Medical His tory Term: Seasonal allergies (molds and spores) Start Date: UNK/UNK/1950 Ongoing: YES | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

1.h Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-23-2020 13:43:23 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 8 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-23-2020 13:43:23 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Seasonal allergies (molds and spo res) | Initial Entry |

1.h Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Sep-23-2020 13:43:23 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/1950 | Initial Entry |

1.h Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Sep-23-2020 13:43:23 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

1.i

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Sep-23-2020 13:43:39 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number 9 : Medical History T Osteoarthritis erm: Start Date: UNK/UNK/2 010 Ongoing: YES | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

1.i Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-23-2020 13:43:39 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 9 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Sep-23-2020 13:43:39 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Osteoarthritis | Initial Entry |

1.i Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Sep-23-2020 13:43:39 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/2010 | Initial Entry |

1.i Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Sep-23-2020 13:43:39 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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Subject Initials: ---

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| <i>I.j</i> | | | | |
|--|-----------------|-------------------------|--|---------------|
| Date | Location | User | Value | Reason |
| Sep-23-2020 13:44:03 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Num 10 ber: Medical History Term: Penicillin allergy (hives) Start Date: UNK/UNK/2000 Ongoing: YES | Initial Entry |
| <i>I.j Line/MH Number:</i> | | | | |
| Date | Location | User | Value | Reason |
| Sep-23-2020 13:44:03 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 10 | Initial Entry |
| <i>I.j Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:</i> | | | | |
| Date | Location | User | Value | Reason |
| Sep-23-2020 13:44:03 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Penicillin allergy (hives) | Initial Entry |
| <i>I.j Start Date:</i> | | | | |
| Date | Location | User | Value | Reason |
| Sep-23-2020 13:44:03 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/2000 | Initial Entry |
| <i>I.j Ongoing:</i> | | | | |
| Date | Location | User | Value | Reason |
| Sep-23-2020 13:44:03 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

I.k

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Sep-23-2020 13:44:25 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Num 11 ber: Medical Histo Amoxicillin aller ry Term: gy (hives) Start Date: UNK/UNK/2000 Ongoing: YES | Initial Entry |

I.k Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------|---------------|
| Sep-23-2020 13:44:25 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 11 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-23-2020 13:44:25 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Amoxicillin allergy (hives) | Initial Entry |

I.k Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Sep-23-2020 13:44:25 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/2000 | Initial Entry |

I.k Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Sep-23-2020 13:44:25 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

I.l

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

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

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Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------------|
| Sep-25-2020 08:52:38 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Line/MH 12 Number: Medical History Term: Inner ear pain 14d post shingles vaccine Start Date: Nov/UNK/2015 Ongoing: NO End Date: Dec/UNK/2015 | Transcription Error |
| Sep-24-2020 09:57:07 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Line/MH Number: 12 Medical History Term: Inner ear pain, tinnitus, vertigo 14d post shingles vaccine Start Date: Nov/UNK/2015 Ongoing: NO End Date: Dec/UNK/2015 | Transcription Error |
| Sep-23-2020 13:46:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 12 Medical History Term: Inner ear pain, tinnitus, vertigo 14d post shingles vaccine resolved w prednisone taper, acupuncture Start Date: Nov/UNK/2015 | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Subject No: 12641195

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|--|--|--|--------------------|--|
| | | | Ongoing: NO | |
| | | | End Date: | |
| | | | Dec/UNK/2015 | |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

1.1 Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------|---------------|
| Sep-23-2020 13:46:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 12 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|---|-----------------------------|--|--|
| Sep-25-2020 09:22:54 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 2: C losed | Discrepancy has been closed. |
| Sep-25-2020 08:52:38 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: A nswered | Transcription Error |
| Sep-25-2020 08:52:38 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entr y: Inner ear p ain 14d po st shingles vaccine | Transcription Error |
| Sep-24-2020 17:28:53 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 2: O pened | Multiple concepts in the term INNER EAR PAIN, TINNITUS, VERTIGO 14D POST SHINGLES VACCINE. Split the term into INNER EAR PAIN and TINNITUS and VERTIGO 14D POST SHINGLES VACCINE and report as 3 separate entries. Thank you. |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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|---|---|-----------------------------|---|---|
| Sep-24-2020 13:46:22 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 1: C losed | Discrepancy has been closed. |
| Sep-24-2020 09:57:07 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: A nswered | Transcription Error |
| Sep-24-2020 09:57:07 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Inner ear p ain, tinnitu s, vertigo 1 4d post shi ngles vacci ne | Transcription Error |
| Sep-24-2020 01:47:17 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 1: O pened | Multiple actions for INNER EAR PAIN, TINNITUS, VERTIGO 14D POST SHINGLES VACCINE RESOLVED W PREDNISONE TAPER, ACUPUNCTURE: Please split the term into INNER EAR PAIN, TINNITUS, VERTIGO 14D POST SHINGLES VACCINE and PREDNISONE TAPER and ACUPUNCTURE and submit as three separate entries. Also move PREDNISONE TAPER to the drug |

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|---|-----------------|---------------------|--|------------------|
| | | | | page. Thank you. |
| Sep-23-2020 13:46:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Inner ear pain, tinnitus, vertigo 14d post shingles vaccine resolved w prednisone taper, acupuncture | Initial Entry |

1.l Start Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------------|---------------|
| Sep-23-2020 13:46:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Nov/UNK/2015 | Initial Entry |

1.l Ongoing:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Sep-23-2020 13:46:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date: Dec/UNK/2015 | Initial Entry |

1.m

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Sep-23-2020 13:47:23 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 13 Medical History: Tubal ligation Term: Start Date: UNK/UNK/1974 | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|--|--|--|---|--|
| | | | Ongoing: NO End Date: UNK/UNK/ 1974 | |
|--|--|--|---|--|

I.m Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------|---------------|
| Sep-23-2020 13:47:23 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 13 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Sep-23-2020 13:47:23 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Tubal ligation | Initial Entry |

I.m Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Sep-23-2020 13:47:23 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/1974 | Initial Entry |

I.m Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-23-2020 13:47:23 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date: UNK/UNK/1974 | Initial Entry |

I.n

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Sep-23-2020 13:47:50 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Numb 14 | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|--|--|--|---|--|
| | | | er: Medical History Skin biopsy (benign) Term: benign Start Date: UNK/UNK/1985 Ongoing: NO End Date: UNK/UNK/1985 | |
|--|--|--|---|--|

1.n Line/MH Number:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------|---------------|
| Sep-23-2020 13:47:50 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 14 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Sep-23-2020 13:47:50 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Skin biopsy (benign) | Initial Entry |

1.n Start Date:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|------------------------------------|---------------|
| Sep-23-2020 13:47:50 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/1985 | Initial Entry |

1.n Ongoing:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Sep-23-2020 13:47:50 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date: UNK/UNK/1985 | Initial Entry |

1.o

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Sep-23-2020 13:48:10 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Num 15 ber: Medical Histor Breast biopsy (b y Term: enign) Start Date: UNK/UNK/201 8 Ongoing: NO End Date: UNK/UNK/2 018 | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

I.o Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------|---------------|
| Sep-23-2020 13:48:10 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 15 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-23-2020 13:48:10 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Breast biopsy (benign) | Initial Entry |

I.o Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Sep-23-2020 13:48:10 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/2018 | Initial Entry |

I.o Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-23-2020 13:48:10 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date: UNK/UNK/2018 | Initial Entry |

I.p

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|---|----------------------------------|
| Sep-25-2020 08:56:38 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Line/MH Numb 16 er: Medical Histor Prednisone ta y Term: per Start Date: Nov/UNK/20 15 | Transcription Error (DELETED) |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|---|-----------------|-------------------------|--|---------------|
| | | | Ongoing: NO End Date: Dec/UNK/2015 | |
| Sep-24-2020 09:58:32 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 16 Medical History Term: Prednisone ta per Start Date: Nov/UNK/2015 Ongoing: NO End Date: Dec/UNK/2015 | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

I.p Line/MH Number:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------|---|
| Sep-25-2020 08:56:38 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> ±6 | Transcription Error (DELETED) |
| Sep-24-2020 09:58:32 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 16 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|---|--------------------------|--|--|
| Sep-28-2020 05:35:57 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Sep-25-2020 08:56:38 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Prednisone taper | Transcription Error (DELETED) |
| Sep-25-2020 08:56:38 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Transcription Error |
| Sep-24-2020 13:58:39 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 1: Opened | Clarify PREDNISONE TAPER as follows...Drug only reported. Are you reporting ALLERGY TO? INTERACTION WITH? Other? Please update |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|---|-----------------|------------------|--|---|
| | | | | the verbatim term to clarify. If reporting therapeutic use, please move the term to the drug page. Thank you. |
| Sep-24-2020 09:58:32 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry : Predni sone t aper | Initial Entry |

1.p Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---|
| Sep-25-2020 08:56:38 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Nov/UNK/2015 | Transcription Error (DELETED) |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

I.p Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Sep-24-2020 09:58:32 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Nov/UNK/2015 | Initial Entry |

I.p Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---|
| Sep-25-2020 08:56:38 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date: Dec/UNK/2015 | Transcription Error (DELETED) |
| Sep-24-2020 09:58:32 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date: Dec/UNK/2015 | Initial Entry |

I.q

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Sep-24-2020 09:58:53 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Numbe 17 r: Medical History Acupuncture Term: Start Date: Nov/UNK/2015 5 Ongoing: NO End Date: Dec/UNK/2015 | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

I.q Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------|---------------|
| Sep-24-2020 09:58:53 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 17 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-24-2020 09:58:53 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Acupuncture | Initial Entry |

I.q Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Sep-24-2020 09:58:53 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Nov/UNK/2015 | Initial Entry |

I.q Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-24-2020 09:58:53 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date: Dec/UNK/2015 | Initial Entry |

I.r

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Sep-25-2020 08:53:27 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 18 Medical History Term: Tinnitus 14d post s hingles vaccine Start Date: Nov/UNK/2015 | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|--|--|--|--|--|
| | | | Ongoing: NO End Date: Dec/UNK/2015 | |
|--|--|--|--|--|

I.r Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------|---------------|
| Sep-25-2020 08:53:27 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 18 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-25-2020 08:53:27 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Tinnitus 14d post shingles vaccin e | Initial Entry |

I.r Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Sep-25-2020 08:53:27 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Nov/UNK/2015 | Initial Entry |

I.r Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-25-2020 08:53:27 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date: Dec/UNK/2015 | Initial Entry |

I.s

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Sep-25-2020 08:54:06 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Nu 19 mber: | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|--|--|--|--|--|
| | | | Medical History Term: Vertigo 14d post shingles vaccine Start Date: Nov/UNK/2015 Ongoing: NO End Date: Dec/UNK/2015 | |
|--|--|--|--|--|

I.s Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------|--------------------------|---------------|
| Sep-25-2020 08:54:06 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 19 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Sep-25-2020 08:54:06 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Vertigo 14d post shingles vaccine | Initial Entry |

I.s Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------------|---------------|
| Sep-25-2020 08:54:06 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Nov/UNK/2015 | Initial Entry |

I.s Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Sep-25-2020 08:54:06 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date: Dec/UNK/2015 | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

1. Select appropriate response - What is the subject HIV status?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-23-2020 13:48:32 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: The subject is NOT known to be HIV POSITIVE | Initial Entry |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-23-2020 13:49:12 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/22/2020 | Initial Entry |

2. Weight:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------|---------------|
| Sep-23-2020 13:49:12 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 102.2 | Initial Entry |

3. Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Sep-23-2020 13:49:12 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: kg | Initial Entry |

4. Height:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------|---------------|
| Sep-23-2020 13:49:12 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 167.5 | Initial Entry |

5. Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Sep-23-2020 13:49:12 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: cm | Initial Entry |

6. Body Mass Index:

| Date | Location | User | Value | Reason |
|----------------------|-----------------|-----------|--------------------|---------------|
| Sep-23-2020 13:49:12 | ACV0PFEINFP6000 | auto calc | Data Entry: | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|--|--|------------|------|--|
| (UTC-08:00) Pacific Time (US & Canada) | | (autocalc) | 36.4 | |
|--|--|------------|------|--|

7.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Sep-23-2020 13:49:12 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier:: 1 Temperature: 36.3 Temperature Unit: C Temperature Location: FOREHEAD | Initial Entry |

7.a Record Identifier:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------------|---------------|
| Sep-23-2020 13:49:12 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

7.a Temperature:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|----------------------------|---------------|
| Sep-23-2020 13:49:12 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 36.3 | Initial Entry |

7.a Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------------|---------------|
| Sep-23-2020 13:49:12 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: C | Initial Entry |

7.a Temperature Location:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Sep-23-2020 13:49:12 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: FOREHEAD | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Lab Panel:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Sep-23-2020 13:49:22 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> URINALYSIS | Initial Entry |

2. Lab Sub-Panel:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Sep-23-2020 13:49:22 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> PREGNANCY | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-23-2020 13:49:22 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sep/22/2020 | Initial Entry |

4. Laboratory Name and Address (Derived)

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Sep-23-2020 13:49:22 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> STUDY SITE | Initial Entry |

5. Specimen Type:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Sep-23-2020 13:49:22 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> URINE | Initial Entry |

6.a

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

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|---|-----------------|-------------------------|--|---------------|
| Sep-23-2020 13:49:22 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined Identifier: Test:: Choriogonadotropin Beta_PX113 Result:: Not Done:: NOT DONE | Initial Entry |
|---|-----------------|-------------------------|--|---------------|

6.a Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------|---------------|
| Sep-23-2020 13:49:22 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 113 | Initial Entry |

6.a Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-23-2020 13:49:22 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Choriogonadotropin Beta_PX113 | Initial Entry |

6.a Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Sep-23-2020 13:49:22 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT DONE | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Randomization Date :

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-25-2020 08:51:23 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/22/2020 | Initial Entry |

2. Randomization Number:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Sep-25-2020 08:51:23 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 264013 | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (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:** 1264**Site Name:** (1264) University of California Davis Health**Subject No:** 12641195**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Data Origin**

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Sep-24-2020 11:14:08 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Sep-24-2020 11:14:08 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|---|
| Sep-24-2020 11:14:18 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Sep-24-2020 11:14:08 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Sep-24-2020 11:14:08 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Sep/22/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-24-2020 11:14:18 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BM92PN | Initial Entry |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Sep-24-2020 11:14:18 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BM92PN | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-24-2020 11:14:31 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BNWC66 | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Sep-24-2020 11:14:31 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BNWC66 | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-24-2020 11:14:39 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BNWC67 | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Sep-24-2020 11:14:39 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BNWC67 | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1264**Subject No:** 12641195**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1264) University of California Davis Health**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Data Origin**

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Sep-24-2020 08:03:42 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Sep-24-2020 08:03:42 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|---|
| Sep-24-2020 08:03:50 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Sep-24-2020 08:03:42 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Sep-24-2020 08:03:42 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Sep/22/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-24-2020 08:03:50 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BM92PJ | Initial Entry |

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: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Sep-24-2020 08:03:50 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BM92PJ | Initial Entry |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Sep-23-2020 13:49:46 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2. Treatment Name

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Sep-23-2020 13:49:46 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BLINDED THERAPY | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Sep-23-2020 13:49:46 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INJECTION | Initial Entry |

4. Dose Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-23-2020 13:49:46 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/22/2020 14:50 | Initial Entry |

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Sep-23-2020 13:49:46 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|----------------------|-----------------|---------|--------------------|---------------|
| Sep-23-2020 13:49:46 | ACV0PFEINFP6000 | (b) (6) | Data Entry: | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|--|--|---------|------|--|
| (UTC-08:00) Pacific Time (US & Canada) | | (b) (4) | LEFT | |
|--|--|---------|------|--|

7. Route:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Sep-23-2020 13:49:46 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Sep-23-2020 13:49:46 (UTC-08:00) Pacific 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-23-2020 13:49:46 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Select appropriate response - Reactogenicity diary collection

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-23-2020 13:49:53 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO - REACTOGENICITY E-DI ARY NOT COLLECTED FOR T HIS SUBJECT | Initial Entry |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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I. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Oct-15-2020 08:59:00 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/14/2020 | Initial Entry |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Oct-16-2020 08:41:44 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/14/2020 | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Oct-16-2020 08:41:44 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier:: 1 Temperature: 36.2 Temperature Unit: C Temperature Locat ion:: FOREHE AD | Initial Entry |

2.a Record Identifier:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Oct-16-2020 08:41:44 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

2.a Temperature:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------|---------------|
| Oct-16-2020 08:41:44 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 36.2 | Initial Entry |

2.a Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------|-------------------------|---------------|
| Oct-16-2020 08:41:44 (UTC-08:00) Pacific | ACV0PFEINFP6000 | (b) (6) | Data Entry: C | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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

2.a Temperature Location:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Oct-16-2020 08:41:44 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: FOREHEAD | Initial Entry |

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Lab Panel:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Oct-16-2020 08:41:57 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> URINALYSIS | Initial Entry |

2. Lab Sub-Panel:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Oct-16-2020 08:41:57 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> PREGNANCY | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Oct-16-2020 08:41:57 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Oct/14/2020 | Initial Entry |

4. Laboratory Name and Address (Derived)

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Oct-16-2020 08:41:57 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> STUDY SITE | Initial Entry |

5. Specimen Type:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Oct-16-2020 08:41:57 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> URINE | Initial Entry |

6.a

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

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|---|-----------------|-------------------------|--|---------------|
| Oct-16-2020 08:41:57 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined Identifier: Test:: Choriogonadotropin Beta_PX113 Result:: Not Done:: NOT DONE | Initial Entry |
|---|-----------------|-------------------------|--|---------------|

6.a Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------|---------------|
| Oct-16-2020 08:41:57 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 113 | Initial Entry |

6.a Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Oct-16-2020 08:41:57 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Choriogonadotropin Beta_PX113 | Initial Entry |

6.a Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Oct-16-2020 08:41:57 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT DONE | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1264**Subject No:** 12641195**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1264) University of California Davis Health**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Data Origin**

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Oct-15-2020 08:59:14 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Oct-15-2020 08:59:14 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|---|
| Oct-15-2020 08:59:26 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Oct-15-2020 08:59:14 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Oct-15-2020 08:59:14 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Oct/14/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Oct-15-2020 08:59:26 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BM92W6 | Initial Entry |

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Oct-15-2020 08:59:26 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BM92W6 | Initial Entry |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Oct-16-2020 08:43:21 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of First Delay: Oct/14/2020 Reason(s) for Temporary Delay of Vaccination FEVER OR ACUTE ILLNES S | Initial Entry |

4. Dose Date Time:

| Date | Location | User | Value | Reason |
|--|---|----------------------|-------------------------------|---|
| Oct-29-2020 04:22:39 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Del eted | Delay in vaccination |
| Oct-18-2020 23:22:13 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Ca ndidat e | DMW5057796;Dose Date is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify |
| Oct-18-2020 23:21:52 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Clo sed | Need to keep in Candidate |
| Oct-18-2020 23:18:56 (UTC-08:00) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY (b) (4) | Query 1: Op ened | DMW5057796;Dose Date is not expected to be Unknown or |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|--|-----------------|---------------------|--|--|
| Pacific Time (US & Canada) | | | | Not Applicable. Please review and update appropriately or clarify |
| Oct-16-2020 08:43:41 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry : Not A pplica ble | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-16-2020 08:43:49 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-16-2020 08:43:56 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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I. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Nov-13-2020 09:45:57 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Nov/13/2020 | 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:** 1264**Site Name:** (1264) University of California Davis Health**Subject No:** 12641195**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Data Origin**

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Nov-16-2020 08:38:07 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Nov-16-2020 08:38:07 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|---|
| Nov-16-2020 08:38:16 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Nov-16-2020 08:38:07 (UTC-08:00) Pacific 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. |
| Nov-16-2020 08:38:07 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Nov/13/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-16-2020 08:38:16 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BM92D6 | 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: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Nov-16-2020 08:38:16 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BM92D6 | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-16-2020 08:38:26 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BRSSHW | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Nov-16-2020 08:38:26 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BRSSHW | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-16-2020 08:38:34 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BRSSHX | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Nov-16-2020 08:38:34 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BRSSHX | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/24/2021

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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I. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Mar-03-2021 12:29:47 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Feb/24/2021 | Initial Entry |

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/24/2021

Form: UNPLANNED VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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I. Assessments

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---------------------------------------|---|
| Mar-03-2021 12:31:02 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Mar-03-2021 12:30:37 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate. |
| Mar-03-2021 12:30:37 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: CONTACT OUTCOME | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/24/2021

Form: CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Contact Type:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Mar-03-2021 12:31:02 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: TELEPHONE VISIT | Initial Entry |

2. Was contact made?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--|--|
| Mar-03-2021 12:32:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Mar-03-2021 12:31:02 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | Contact Outcome' is selected as 'VISIT ARRANGED' but no 'VITAL SIGNS' and/or 'UNPLANNED ASSESSMENT OF LOCAL REACTION' form(s) is/are entered. Please review and update as appropriate. |
| Mar-03-2021 12:31:02 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Contact: Feb/24/2021 Contact Outcome: VISIT ARRANGED | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001**Visit:** Unplanned 1 - Unscheduled Visit on Feb/24/2021**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History**Form Version:** 20-Feb-2021 02:16**Form Status:** Data Complete, Frozen, Verified**Site No:** 1264**Site Name:** (1264) University of California Davis Health**Subject No:** 12641195**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**I. Date:**

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|-----------------------------------|--|
| Mar-03-2021 12:33:17 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Closed | Close Auto Query |
| Mar-03-2021 12:33:17 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Mar-03-2021 12:33:17 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Feb/24/2021 | Transcription Error |
| Mar-03-2021 12:32:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Opened | Vital Signs Date is not equal to Date of Assessment for the Unplanned Assessment of Local Reaction at the same unplanned visit. Please review and correct as appropriate or clarify. |
| Mar-03-2021 12:31:49 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | Collection Date, 24/Mar/2021 is a future date relative to when it was entered on 03/Mar/2021. Please correct. |
| Mar-03-2021 12:31:49 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Mar/24/2021 | Initial Entry |

2.a

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

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/24/2021

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:16

Form Status: Data Complete, Frozen, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|---|-----------------|---------------------|---|---------------|
| Mar-03-2021 12:31:49 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier:: 1 Temperature: 36.5 Temperature Unit: C Temperature Locat ion:: AD | Initial Entry |
|---|-----------------|---------------------|---|---------------|

2.a Record Identifier:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Mar-03-2021 12:31:49 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

2.a Temperature:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------|---------------|
| Mar-03-2021 12:31:49 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 36.5 | Initial Entry |

2.a Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Mar-03-2021 12:31:49 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: C | Initial Entry |

2.a Temperature Location:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Mar-03-2021 12:31:49 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: FOREHEAD | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/24/2021

Form Version: 20-Feb-2021 02:13

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date of Assessment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Mar-03-2021 12:32:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Feb/24/2021 | Initial Entry |

2. Injection Site Location

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Mar-03-2021 12:32:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

3. Injection Site Body Side:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------|---------------|
| Mar-03-2021 12:33:38 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: LEFT | Initial Entry |

4.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Mar-03-2021 12:32:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Reaction:: REDNESS Reaction Present:: NO | Initial Entry |

4.a Reaction:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------------|---------------|
| Mar-03-2021 12:32:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: REDNESS | Initial Entry |

4.a Reaction Present:

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

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/24/2021

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:13

Form Status: Data Complete, Frozen, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|---|-----------------|---------------------|--------------------------|---------------|
| Mar-03-2021 12:32:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |
|---|-----------------|---------------------|--------------------------|---------------|

4.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Mar-03-2021 12:32:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Reaction:: SWELLIN G Reaction Present: NO : | Initial Entry |

4.b Reaction:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Mar-03-2021 12:32:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: SWELLING | Initial Entry |

4.b Reaction Present:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Mar-03-2021 12:32:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Mar-03-2021 12:32:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: PAIN AT INJECT ION SITE Symptom Pr NO esent:: | Initial Entry |

5.a Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------|--|---------------|
| Mar-03-2021 12:32:51 (UTC-08:00) Pacific | ACV0PFEINFP6000 | (b) (6) | Data Entry: PAIN AT INJECTION SITE | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/24/2021

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:13

Form Status: Data Complete, Frozen, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

5.a Symptom Present:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Mar-03-2021 12:32:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Mar-03-2021 12:32:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: FATIGUE/TIRE DNESS Symptom Pre NO sent:: | Initial Entry |

5.b Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Mar-03-2021 12:32:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: FATIGUE/TIREDNESS | Initial Entry |

5.b Symptom Present:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Mar-03-2021 12:32:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Mar-03-2021 12:32:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: HEADACH E Symptom Present NO :: | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/24/2021

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:13

Form Status: Data Complete, Frozen, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.c Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Mar-03-2021 12:32:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: HEADACHE | Initial Entry |

5.c Symptom Present:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Mar-03-2021 12:32:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Mar-03-2021 12:32:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: VOMITIN G Symptom Present: NO : | Initial Entry |

5.d Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Mar-03-2021 12:32:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: VOMITING | Initial Entry |

5.d Symptom Present:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Mar-03-2021 12:32:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

5.e

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

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/24/2021

Form Version: 20-Feb-2021 02:13

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|---|-----------------|---------------------|--|---------------|
| Mar-03-2021 12:32:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: DIARRHE A Symptom Present NO :: | Initial Entry |
|---|-----------------|---------------------|--|---------------|

5.e Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Mar-03-2021 12:32:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: DIARRHEA | Initial Entry |

5.e Symptom Present:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Mar-03-2021 12:32:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

5.f

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Mar-03-2021 12:32:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom NEW OR WORSEN :: ED MUSCLE PAIN Symptom NO Present:: | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/24/2021

Form Version: 20-Feb-2021 02:13

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

5.f Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Mar-03-2021 12:32:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR WORSENE D MUSCLE PAIN | Initial Entry |

5.f Symptom Present:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Mar-03-2021 12:32:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

5.g

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Mar-03-2021 12:32:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom: NEW OR WORSE : NED JOINT PAIN Symptom NO Present:: | Initial Entry |

5.g Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Mar-03-2021 12:32:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR WORSENE D JOINT PAIN | Initial Entry |

5.g Symptom Present:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Mar-03-2021 12:32:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

5.h

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

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/24/2021

Form Version: 20-Feb-2021 02:13

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|---|-----------------|---------------------|--|---------------|
| Mar-03-2021 12:32:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: CHILLS Symptom Present:: NO | Initial Entry |
|---|-----------------|---------------------|--|---------------|

5.h Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Mar-03-2021 12:32:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: CHILLS | Initial Entry |

5.h Symptom Present:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Mar-03-2021 12:32:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|--------|
| Oct-30-2020 15:22:08 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|--------|
| Oct-30-2020 15:25:07 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|--------|
| Oct-30-2020 15:27:06 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|--------|
| Oct-30-2020 15:28:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|--------|
| Nov-04-2020 11:18:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|--------|
| Nov-04-2020 11:20:23 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|--------|
| Nov-04-2020 11:21:53 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Oct-30-2020 15:22:08 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Oct-30-2020 15:22:08 (UTC-08:00) Pacific 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-30-2020 15:22:08 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Cheilitis | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Oct-30-2020 15:22:08 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/7/2020 UNK:UNK | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|-----------------------------|
| Nov-13-2020 14:27:23 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date Time: Nov/9/2020 UNK:UNK | New Information |
| Nov-10-2020 09:18:36 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|---|-----------------|---------------------|---------------------------|--|
| Nov-09-2020 13:08:16 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Per last contact w/subject event is ongoing. |
| Nov-09-2020 12:37:53 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | ClinQuery: Please advise if this event is still ongoing? |
| Oct-30-2020 15:22:08 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Oct-30-2020 15:22:08 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 2 | Initial Entry |

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Oct-30-2020 15:22:08 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

8. Is this adverse event the result of a study Medication Error?

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Oct-30-2020 15:22:08 (UTC-08:00) Pacific 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 |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|---|-----------------|---------------------|-------------------------------|---------------|
| Oct-30-2020 15:22:08 (UTC-08:00) Pacific 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 |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-30-2020 15:22:08 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Oct-30-2020 15:22:08 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Oct-30-2020 15:22:08 (UTC-08:00) Pacific 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 |
|---|-----------------|---------------------------|--|--|
| Nov-13-2020 14:27:39 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Nov-13-2020 14:27:39 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RECOVERED/RESOLVED | New Information |
| Nov-13-2020 14:27:23 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | For AE Cheilitis: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|---|-----------------|---------------------|--|---------------|
| | | | | present. |
| Oct-30-2020 15:22:08 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT RECOVERED/NOT RES OLVED | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Oct-30-2020 15:22:08 (UTC-08:00) Pacific 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

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Oct-30-2020 15:25:07 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Oct-30-2020 15:25:07 (UTC-08:00) Pacific 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 |
|---|-----------------|---------------------|---------------------------------|---------------|
| Oct-30-2020 15:25:07 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Dry mouth | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Oct-30-2020 15:25:07 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/7/2020 UNK:UNK | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------|--|
| Nov-10-2020 09:18:36 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Nov-09-2020 13:08:29 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Per last contact w/subject event is ongoing. |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|---|-----------------|---------------------|---------------------------|--|
| Nov-09-2020 12:38:49 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | ClinQuery: Please advise if this event is still ongoing? |
| Oct-30-2020 15:25:07 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Oct-30-2020 15:25:07 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 2 | Initial Entry |

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Oct-30-2020 15:25:07 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

8. Is this adverse event the result of a study Medication Error?

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Oct-30-2020 15:25:07 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

9. Is this event related to study treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------------|---------------|
| Oct-30-2020 15:25:07 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RELATED | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|-------------------|
| Dec-03-2020 09:48:13 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: DRUG WITHDRAWN | Query resolution. |
| Oct-30-2020 15:25:07 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Oct-30-2020 15:25:07 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Oct-30-2020 15:25:07 (UTC-08:00) Pacific 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 |
|---|-----------------|---------------------|--|---------------|
| Oct-30-2020 15:25:07 (UTC-08:00) Pacific 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 |
|---|-----------------|---------------------|--------------------------|---------------|
| Oct-30-2020 15:25:07 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Oct-30-2020 15:27:06 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Oct-30-2020 15:27:06 (UTC-08:00) Pacific 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 |
|---|-----------------|---------------------|---|--|
| Dec-18-2020 12:58:24 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Dec-18-2020 12:12:46 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Original value is correct |
| Dec-16-2020 08:30:42 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | pls update AE term to indicate location ie general or list specific body parts. Thanks |
| Dec-16-2020 08:12:45 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Pruritus, abdomen | Transcription Error |
| Oct-30-2020 15:27:06 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Pruritus | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

4. Start Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Oct-30-2020 15:27:06 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/7/2020 UNK:UNK | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---------------------------|--|
| Nov-10-2020 09:18:36 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Nov-09-2020 13:09:12 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Per last contact w/subject event is ongoing. |
| Nov-09-2020 12:39:58 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | ClinQuery: Please advise if this event is still ongoing? |
| Oct-30-2020 15:27:06 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------------|---------------|
| Oct-30-2020 15:27:06 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 2 | Initial Entry |

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

| Date | Location | User | Value | Reason |
|----------------------|-----------------|---------|--------------------|---------------|
| Oct-30-2020 15:27:06 | ACV0PFEINFP6000 | (b) (6) | Data Entry: | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|--|--|---------|----|--|
| (UTC-08:00) Pacific Time (US & Canada) | | (b) (4) | NO | |
|--|--|---------|----|--|

**8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.**

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Oct-30-2020 15:27:06 (UTC-08:00) Pacific 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 |
|--|-----------------|------------------|-------------------|---|
| Jan-29-2021 11:57:08 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Closed | Response satisfies query |
| Jan-29-2021 11:46:06 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Answered | Rationale is that it was a change in patient's status, after vaccination, without another clearly identifiable cause. |
| Jan-20-2021 10:37:58 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | clinical: reissued |
| Jan-20-2021 10:35:04 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Opened | clinical: pls advise on rationale for determining as 'related' given start date is several weeks post vaccination. Thanks |
| Jan-06-2021 09:57:09 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened | clinical: pls advise on rationale for determining as 'related' given start date is several weeks post vaccination. Thanks |

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|---|-----------------|---------------------|-------------------------------|---|
| Jan-06-2021 09:56:07 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | clinical:reissued. |
| Dec-18-2020 05:33:58 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | clinical: pls advise on rationale for determining as 'related' given start date is several weeks post vaccination. Thanks |
| Oct-30-2020 15:27:06 (UTC-08:00) Pacific 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 |
|---|-----------------|---------------------|--------------------------------------|-------------------|
| Dec-03-2020 09:48:32 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: DRUG WITHDRAWN | Query resolution. |
| Oct-30-2020 15:27:06 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Oct-30-2020 15:27:06 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Oct-30-2020 15:27:06 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

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

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

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Subject No: 12641195

Generated By: (b) (4)

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Form Status: Data Complete

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|---|-----------------|---------------------|--|---------------|
| Oct-30-2020 15:27:06 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT RECOVERED/NOT RESO LVED | Initial Entry |
|---|-----------------|---------------------|--|---------------|

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Oct-30-2020 15:27:06 (UTC-08:00) Pacific 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

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Oct-30-2020 15:28:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Oct-30-2020 15:28:51 (UTC-08:00) Pacific 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 |
|---|-----------------|---------------------------|--|--|
| Dec-16-2020 08:30:16 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Dec-16-2020 08:11:24 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Transcription Error |
| Dec-16-2020 08:11:24 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Rash maculo-papular, abdomen | Transcription Error |
| Dec-07-2020 09:29:38 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | clinical: pls update AE term for AE 3 and 4 to indicate location ie general or list specific body parts. Thanks |
| Oct-30-2020 15:28:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Rash maculo-papular | Initial Entry |

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

4. Start Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Oct-30-2020 15:28:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/7/2020 UNK:UNK | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---------------------------|--|
| Nov-10-2020 09:18:36 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Nov-09-2020 13:09:21 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Per last contact w/subject event is ongoing. |
| Nov-09-2020 12:40:27 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | ClinQuery: Please advise if this event is still ongoing? |
| Oct-30-2020 15:28:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------------|---------------|
| Oct-30-2020 15:28:51 (UTC-08:00) Pacific 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 |
|----------------------|-----------------|---------|--------------------|---------------|
| Oct-30-2020 15:28:51 | ACV0PFEINFP6000 | (b) (6) | Data Entry: | Initial Entry |

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Header Text: c4591001

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Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|--|--|---------|----|--|
| (UTC-08:00) Pacific Time (US & Canada) | | (b) (4) | NO | |
|--|--|---------|----|--|

8. Is this adverse event the result of a study Medication Error?

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

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Oct-30-2020 15:28:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

9. Is this event related to study treatment:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-------------------|---|
| Jan-29-2021 12:01:57 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Closed | Response satisfies query |
| Jan-29-2021 11:45:25 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Answered | Rationale is that it was a change in patient's status, after vaccination, without another clearly identifiable cause. |
| Jan-20-2021 10:37:23 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | clinical: reissued |
| Jan-20-2021 10:36:08 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Opened | clinical: pls advise on rationale for determining as 'related' given start date is several weeks post vaccination. Thanks |
| Jan-06-2021 09:58:00 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened | clinical: pls advise on rationale for determining as 'related' given start date is several weeks post vaccination. |

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Header Text: c4591001

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Subject No: 12641195

Generated By: (b) (4)

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Form Status: Data Complete

Site Name: (1264) University of California Davis Health

Subject Initials: ---

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|---|-----------------|---------------------|-------------------------------|--|
| | | | | Thanks |
| Jan-06-2021 09:57:41 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | clinical: reissued. |
| Dec-07-2020 09:31:26 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | clinical: pls advise on rationale for determining as 'related' given start date is several weeks post vaccination. Thanks |
| Oct-30-2020 15:28:51 (UTC-08:00) Pacific 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 |
|---|-----------------|---------------------|--------------------------------------|-------------------|
| Dec-03-2020 09:48:55 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: DRUG WITHDRAWN | Query resolution. |
| Oct-30-2020 15:28:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Oct-30-2020 15:28:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Oct-30-2020 15:28:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

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

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

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Subject No: 12641195

Generated By: (b) (4)

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Form Status: Data Complete

Site Name: (1264) University of California Davis Health

Subject Initials: ---

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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Oct-30-2020 15:28:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT RECOVERED/NOT RESO LVED | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Oct-30-2020 15:28:51 (UTC-08:00) Pacific 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

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Nov-04-2020 11:18:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Nov-04-2020 11:18:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 5 | Initial Entry |

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|---------------|
| Nov-04-2020 11:18:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Hyperosmia | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-04-2020 11:18:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/7/2020 UNK:UNK | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|-----------------------------|
| Nov-13-2020 14:26:15 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date Time: Nov/13/2020 UNK:UNK | New Information |
| Nov-10-2020 09:18:36 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |

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Header Text: c4591001

Visit: Logs - Unscheduled

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Subject No: 12641195

Generated By: (b) (4)

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Form Status: Data Complete, Locked, Frozen

Site Name: (1264) University of California Davis Health

Subject Initials: ---

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| | | | | |
|---|-----------------|---------------------|---------------------------|--|
| Nov-09-2020 13:08:39 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Per last contact w/subject event is ongoing. |
| Nov-09-2020 12:41:19 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | ClinQuery: Please advise if this event is still ongoing? |
| Nov-04-2020 11:18:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Nov-04-2020 11:18:51 (UTC-08:00) Pacific 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 |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-04-2020 11:18:51 (UTC-08:00) Pacific 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 |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-04-2020 11:18:51 (UTC-08:00) Pacific 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 |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

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Generated By: (b) (4)

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Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|---|-----------------|---------------------|-------------------------------|---------------|
| Nov-04-2020 11:18:51 (UTC-08:00) Pacific 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 |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-04-2020 11:18:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-04-2020 11:18:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-04-2020 11:18:51 (UTC-08:00) Pacific 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 |
|---|-----------------|---------------------------|--|---|
| Nov-13-2020 14:26:43 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Nov-13-2020 14:26:43 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RECOVERED/RESOLVED | New Information |
| Nov-13-2020 14:26:15 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | For AE Hyperosmia: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is |

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Subject Initials: ---

Generated By: (b) (4)

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| | | | | |
|---|-----------------|---------------------|--|---------------|
| | | | | present. |
| Nov-04-2020 11:18:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT RECOVERED/NOT RES OLVED | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-04-2020 11:18:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

Header Text: c4591001

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Subject Initials: ---

Generated By: (b) (4)

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1. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Nov-04-2020 11:20:23 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Nov-04-2020 11:20:23 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 6 | Initial Entry |

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-04-2020 11:20:23 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Worsening eczema | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-04-2020 11:20:23 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/7/2020 UNK:UNK | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------|--|
| Nov-10-2020 09:18:36 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Nov-09-2020 13:08:50 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Per last contact w/subject event is ongoing. |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|---|-----------------|---------------------|---------------------------|--|
| Nov-09-2020 12:42:14 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | ClinQuery: Please advise if this event is still ongoing? |
| Nov-04-2020 11:20:23 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Nov-04-2020 11:20:23 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 2 | Initial Entry |

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-04-2020 11:20:23 (UTC-08:00) Pacific 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 |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-04-2020 11:20:23 (UTC-08:00) Pacific 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 |
|---|-----------------|---------------------|-------------------------------|---------------|
| Nov-04-2020 11:20:23 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RELATED | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|-------------------|
| Dec-03-2020 09:49:19 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: DRUG WITHDRAWN | Query resolution. |
| Nov-04-2020 11:20:23 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-04-2020 11:20:23 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-04-2020 11:20:23 (UTC-08:00) Pacific 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 |
|---|-----------------|---------------------|--|---------------|
| Nov-04-2020 11:20:23 (UTC-08:00) Pacific 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 |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-04-2020 11:20:23 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Nov-04-2020 11:21:53 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Nov-04-2020 11:21:53 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 7 | Initial Entry |

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

| Date | Location | User | Value | Reason |
|---|---|-----------------------------|---------------------------------|---|
| Nov-05-2020 18:35:44 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 1: Clo sed | Discrepancy has been closed. |
| Nov-05-2020 11:38:17 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Ans wered | Transcription Error |
| Nov-05-2020 11:38:17 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Dysgeusia | Transcription Error |
| Nov-04-2020 15:48:28 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 1: Ope ned | Clarify DYSGUESIA as follow... this term appears to be misspelled. Are you |

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|---|-----------------|---------------------|---------------------------------|--|
| | | | | reporting DYSGEUSIA? If so, please edit it to such. Otherwise, please further clarify. Thank you. |
| Nov-04-2020 11:21:53 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Dysguesia | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-04-2020 11:21:53 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/7/2020 UNK:UNK | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|--|
| Nov-13-2020 14:28:14 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date Time: Nov/13/2020 UNK:UNK | New Information |
| Nov-10-2020 09:18:36 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Nov-09-2020 13:09:01 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Per last contact w/subject event is ongoing. |
| Nov-09-2020 12:43:11 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | ClinQuery: Please advise if this event is still ongoing? |
| Nov-04-2020 11:21:53 (UTC-08:00) Pacific | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Nov-04-2020 11:21:53 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> 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 |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-04-2020 11:21:53 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

8. Is this adverse event the result of a study Medication Error?

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-04-2020 11:21:53 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

9. Is this event related to study treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------------|---------------|
| Nov-04-2020 11:21:53 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> RELATED | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-04-2020 11:21:53 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NOT APPLICABLE | Initial Entry |

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

11. Was a Concomitant Medication given?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-04-2020 11:21:53 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-04-2020 11:21:53 (UTC-08:00) Pacific 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 |
|---|-----------------|---------------------------|--|---|
| Nov-13-2020 14:28:26 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Nov-13-2020 14:28:26 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RECOVERED/RESOLVED | New Information |
| Nov-13-2020 14:28:14 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | For AE Dysgeusia : Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present. |
| Nov-04-2020 11:21:53 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT RECOVERED/NOT RES OLVED | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-04-2020 11:21:53 (UTC-08:00) Pacific | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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

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, Frozen, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date of Completion/Discontinuation/Death :

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------------|
| Nov-16-2020 09:17:34 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/14/2020 | Transcription Error |
| Nov-13-2020 09:46:47 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Nov/13/2020 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------------|---------------|
| Nov-13-2020 09:46:47 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: VACCINATION | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------------|-------------------------------------|---|
| Dec-03-2020 09:45:37 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 3: Closed | Close Auto Query |
| Dec-03-2020 09:45:17 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 3: Opened | Response to "Status" is ADVERSE EVENT but "Specify Status" is Provided. |
| Dec-03-2020 09:45:17 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ADVERSE EVENT | Query resolution. |
| Nov-16-2020 11:57:48 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | Hayley Wyper (b) (4) | Query 1: Closed | Response satisfies query |
| Nov-16-2020 09:20:03 (UTC-08:00) Pacific | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Closed | Close Auto Query |

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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, Frozen, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|---|-----------------|------------------------|--|---|
| Time (US & Canada) | | | | |
| Nov-16-2020 09:17:14 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Opened | Response to "Status" is NO LONGER MEETS ELIGIBILITY CRITERIA but "Specify Status" is missing. |
| Nov-16-2020 09:17:14 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Transcription Error |
| Nov-16-2020 09:17:14 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO LONGER MEETS ELIGIBILITY CRITERIA | Transcription Error |
| Nov-14-2020 10:06:37 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | Hayley Wyper (b) (4) | Query 1: Opened | CLINQUERY: This field should capture the reason the subject did not receive the second vaccination. A status of 'completed' requires both vaccinations and V3 to be completed. Please review and update STATUS plus discontinuation DATE on this page |
| Nov-13-2020 09:46:47 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |

4. Specify Status:

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------|-----------------|--------------------------|
| Dec-03-2020 09:50:25 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | Hayley Wyper (b) (4) | Query 2: Closed | Response satisfies query |

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, Frozen, Verified**Site No:** 1264**Site Name:** (1264) University of California Davis Health**Subject No:** 12641195**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51

| | | | | |
|---|-----------------|----------------------------|--------------------------|--|
| Dec-03-2020 09:45:37 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Answered | Query resolution. |
| Dec-03-2020 09:45:37 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Query resolution. |
| Nov-30-2020 11:48:29 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | Hayley Wyper (b) (4) | Query 2: Reissued:Opened | CLINQUERY: The symptoms described are captured as adverse events. AEs should be captured as reason for EOT (status ADVERSE EVENT), and the AE updated at Q10 on the log to indicate DRUG WITHDRAWN. Per guidelines, AEs should take priority for EOT reporting |
| Nov-30-2020 08:40:55 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | Per PI review, subject will not receive further study intervention due to reported symptoms: eczema flare-up, dry mouth, chapped lips, itching, rash. |
| Nov-27-2020 05:51:21 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | Hayley Wyper (b) (4) | Query 2: Opened | CLINQUERY: Please clarify in query response the event related to exclusion 1 and decision to end treatment. |
| Nov-16-2020 11:57:48 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | Hayley Wyper (b) (4) | Query 1: Closed | Response satisfies query |
| Nov-16-2020 11:33:01 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Changed Information |

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, Frozen, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|---|-----------------|----------------------------|--|---|
| Nov-16-2020 11:33:01 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Excl. 1 No further study intervention but will remain in the study to be evaluated for safety. | Changed Information |
| Nov-16-2020 10:33:02 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | Hayley Wyper (b) (4) | Query 1: Opened | CLINQUERY: Status for end of treatment is selected as NO LONGER MEETS ELIGIBILITY CRITERIA. Please clarify which inclusion/exclusion criterion was no longer met in this field. |
| Nov-16-2020 09:20:03 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: will not receive further study intervention but will remain in the study to be evaluated for safety. | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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I. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Feb-09-2021 12:46:50 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/30/2021 | Initial Entry |

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History

Form Status: Data Complete, Frozen

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Feb-09-2021 12:47:02 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Participant is willing to return fo r Vaccination 3 Participant is: eligible per local/national rec ommendations and confirmed to have received only placebo at Vaccination 1/2 | Initial Entry |

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date Treatment Unblinded :

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Feb-09-2021 12:46:40 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/30/2021 | Initial Entry |

2. Primary Reason for Unblinding:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Feb-09-2021 12:46:40 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ASSESS ELIGIBILITY FOR A DDITIONAL VACCINATION | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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I. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------------|
| Mar-04-2021 10:52:41 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Mar/3/2021 | Transcription Error |
| Feb-24-2021 15:36:18 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Feb/24/2021 | Initial Entry |

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION - eCRF
Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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I. Consent Was:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--|---|
| Mar-04-2021 10:53:35 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Mar-04-2021 10:53:35 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: OBTAINED Date Written Consent Obtained Mar/3/2021 | Transcription Error |
| Mar-04-2021 10:52:41 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | Date Informed Consent Obtained is not the same as the Date of Visit. Please correct as necessary. |
| Feb-24-2021 15:40:34 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: OBTAINED Date Written Consent Obtained Feb/24/2021 | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date of Completion/Discontinuation/Death :

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------------|
| Mar-04-2021 10:53:55 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Mar/3/2021 | Transcription Error |
| Feb-24-2021 15:41:03 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Feb/24/2021 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Feb-24-2021 15:41:03 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: REPEAT SCREENING 1 | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------------|---------------|
| Feb-24-2021 15:41:03 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 20-Feb-2021 02:14

Form Status: Data Complete, Frozen, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Lab Panel:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Feb-24-2021 15:41:20 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> URINALYSIS | Initial Entry |

2. Lab Sub-Panel:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Feb-24-2021 15:41:20 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> PREGNANCY | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------------|
| Mar-04-2021 10:54:07 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Mar/3/2021 | Transcription Error |
| Feb-24-2021 15:41:20 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Feb/24/2021 | Initial Entry |

4. Laboratory Name and Address (Derived)

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Feb-24-2021 15:41:20 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> STUDY SITE | Initial Entry |

5. Specimen Type:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Feb-24-2021 15:41:20 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> URINE | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 20-Feb-2021 02:14

Form Status: Data Complete, Frozen, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

6.a

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Feb-24-2021 15:41:20 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: Not Done:: NOT DONE | Initial Entry |

6.a Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------|---------------|
| Feb-24-2021 15:41:20 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 113 | Initial Entry |

6.a Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Feb-24-2021 15:41:20 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Choriogonadotropin Beta_PX113 | Initial Entry |

6.a Not Done:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Feb-24-2021 15:41:20 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT DONE | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Feb-24-2021 15:41:42 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Feb-24-2021 15:41:42 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---------------------------|--|
| Mar-09-2021 21:49:13 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | Response satisfies query |
| Mar-09-2021 10:04:02 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | Per CRA: It is confirmed - you do not need to repeat the swabs or blood draw if within 7 days per protocol. |
| Mar-09-2021 03:09:19 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Reissued: Opened | Please clarify date mismatch and add the reason on the CRF in the 'If no sample collected or sample was not collected according to protocol, please provide reason' field. |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|---|---|------------------------|---|--|
| Mar-08-2021 13:56:20 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | Date is correct |
| Mar-05-2021 21:36:05 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY (b) (4) | Query 2: Opened | DMW7625070;Date of Collection is not equal to Date of Visit. Please clarify or correct. |
| Feb-24-2021 15:41:55 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Feb-24-2021 15:41:42 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Feb-24-2021 15:41:42 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry : YES Date of Collection: Feb/24/2021 | Initial Entry |

5.a

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

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|---|-----------------|---------------------|--|---------------|
| Feb-24-2021 15:41:55 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BR4FBV | Initial Entry |
|---|-----------------|---------------------|--|---------------|

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Feb-24-2021 15:41:55 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BR4FBV | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Feb-24-2021 15:42:07 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BSGR87 | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Feb-24-2021 15:42:07 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BSGR87 | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Feb-24-2021 15:42:18 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BSGR88 | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Feb-24-2021 15:42:18 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BSGR88 | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Feb-24-2021 15:42:35 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Feb-24-2021 15:42:35 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|---|
| Feb-24-2021 15:42:46 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Feb-24-2021 15:42:35 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Feb-24-2021 15:42:35 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Feb/24/2021 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Feb-24-2021 15:42:46 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BRFHBG | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Feb-24-2021 15:42:46 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BRFHBG | Initial Entry |

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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I. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--------------------------|---|
| Mar-10-2021 22:43:56 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Mar-10-2021 13:26:06 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Initial Entry |
| Mar-10-2021 13:26:06 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |
| Mar-10-2021 13:23:37 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |
| Mar-10-2021 07:54:52 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Opened | DM: If a Form Level comment was added and needs to be removed, click on the Form Level comment icon once again to open the comment window. Click on the eraser icon at the right of the screen and click "Submit". Refer to 4.11 of CRFCGs. |
| Mar-09-2021 10:07:10 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | I am unable to edit the VACCINE TRT data, please advise how to edit |
| Mar-09-2021 03:06:30 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | Same Query present |
| Mar-09-2021 00:14:30 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Opened | DM: Page is not frozen. Please review and update |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|---|-----------------|------------------|-----------------------------|--|
| | | | | data. |
| Mar-08-2021 11:49:58 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Please unfreeze as it is not allowing me to change data |
| Mar-05-2021 06:41:43 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Reissued:Candidate | Pending open query present for form to be unfrozen |
| Mar-05-2021 04:09:01 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Opened | DM: Page has been unfrozen. Please update. |
| Mar-04-2021 10:55:44 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | Please unfreeze VACCINE TRT for V101 |
| Mar-04-2021 10:55:21 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Please unfreeze VACCINE TRT. |
| Mar-04-2021 03:23:13 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened | DM: Per comment, visit101 is unfrozen. Please verify and update accordingly. |
| Mar-04-2021 02:56:30 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Opened | DM 1: Per the response please verify and update data of vaccination on this page. Thank you. |
| Mar-03-2021 11:38:29 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Subject's V101VAX3 visit was on 26Feb2021 but Vaccine was not administered. Subject's vaccine administration visit is today. Should I enter the Vaccination information in this visit? |
| Mar-01-2021 03:19:43 | ACV0PFEINFP6000 | (b) (6) | Query 1: Opened | DM: Per comment, |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|---|-----------------|------------------|--------------------------------|--|
| (UTC-08:00) Pacific Time (US & Canada) | | (b) (4) | | please verify and update data for this form. Else clarify. |
| Feb-24-2021 23:57:18 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Candidate | Subject is rescheduled for Vaccination on 26February2021. |
| Feb-24-2021 15:52:10 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

2. Treatment Name

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------|--------------------------------|---------------|
| Mar-10-2021 13:26:06 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BNT162b2 | Initial Entry |
| Mar-10-2021 13:23:37 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |
| Feb-24-2021 15:52:10 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------|---------------------------------|---------------|
| Mar-10-2021 13:26:06 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INJECTION | Initial Entry |
| Mar-10-2021 13:23:37 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |
| Feb-24-2021 15:52:10 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

4. Dose Date Time:

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

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|---|-----------------|------------------|--|---------------|
| Mar-10-2021 13:26:06 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Mar/3/2021 10:14 | Initial Entry |
| Mar-10-2021 13:23:37 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |
| Feb-24-2021 15:52:10 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Mar-10-2021 13:26:06 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |
| Mar-10-2021 13:23:37 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |
| Feb-24-2021 15:52:10 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Mar-10-2021 13:26:06 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: LEFT | Initial Entry |
| Mar-10-2021 13:23:37 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |
| Feb-24-2021 15:52:10 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

7. Route:

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

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Mar-10-2021 13:26:06 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |
| Mar-10-2021 13:23:37 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |
| Feb-24-2021 15:52:10 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

8. Actual Dose:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------|---------------|
| Mar-10-2021 13:26:06 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 30.0 | Initial Entry |
| Mar-10-2021 13:23:37 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |
| Feb-24-2021 15:52:10 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

9. Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------|---------------|
| Mar-10-2021 13:26:06 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ug | Initial Entry |
| Mar-10-2021 13:23:37 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |
| Feb-24-2021 15:52:10 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

10. Timeframe Subject Was Observed

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

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Mar-10-2021 13:26:06 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 30 MINUTES | Initial Entry |
| Mar-10-2021 13:23:37 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |
| Feb-24-2021 15:52:10 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Mar-10-2021 13:26:06 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |
| Mar-10-2021 13:23:37 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |
| Feb-24-2021 15:52:10 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

1. Subject Status

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------------|
| Dec-03-2020 09:45:17 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DISCONTINUED | Query resolution. |
| Nov-16-2020 09:17:14 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DISCONTINUED | Transcription Error |
| Nov-13-2020 09:46:47 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: FOLLOW-UP | Initial Entry |
| Sep-25-2020 08:51:23 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ENROLLED/RANDOMIZED | Initial Entry |
| Sep-23-2020 13:40:07 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SCREENED | Initial Entry |

2. Subject Status Date

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------------|---------------------|
| Dec-03-2020 09:45:17 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Oct/14/2020 | Query resolution. |
| Nov-16-2020 09:17:34 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Oct/14/2020 | Transcription Error |
| Nov-16-2020 09:17:14 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Nov/13/2020 | Transcription Error |
| Nov-13-2020 09:46:47 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Nov/13/2020 | Initial Entry |
| Sep-25-2020 08:51:23 (UTC-08:00) Pacific | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sep/22/2020 | Initial Entry |

090177e196ae300a\Final\Final On: 01-Apr-2021 03:58 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1264

Subject No: 12641195

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1264) University of California Davis Health

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

| | | | | |
|---|-----------------|-------------------------|-----------------------------------|---------------|
| Time (US & Canada) | | | | |
| Sep-23-2020 13:40:07 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sep/22/2020 | Initial Entry |

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641195

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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I. Casebook Signature

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------------|--|---------------|
| Oct-26-2020 16:58:54 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | Timothy Albertson (b) (4) | Data Entry: Click Here to Enable | Initial Entry |