

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Cohort Selection

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

| | | |
|----|---|-----------------|
| 1. | Select appropriate response - Protocol version | 01 DEC 2020 |
| 2. | Select appropriate response - What cohort does the subject belong to? | STAGE 3 COHORTS |

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Informed Consent

| | | |
|----|--------------|--|
| 1. | Consent Was: | OBTAINED Date Written Consent Obtained Dec/18/2020 |
|----|--------------|--|

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Demography

| | | |
|----|---------------------------------|--|
| 1. | Subject ID | [10391285] |
| 2. | Birth Date: | (b) (6) /2007 |
| 3. | Sex: | FEMALE |
| 4. | Ethnicity: | NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN |
| 5. | Race: (Check X all that apply): | WHITE |
| 6. | Racial Designation: | |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Disposition - Screening

| | | |
|----|--|-------------|
| 1. | Date of Completion/Discontinuation/Death | Dec/18/2020 |
| 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: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Medical History Details

| | | |
|-----|--|-----------------------|
| 1.a | Line/MH Number: | [1] |
| | Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies: | [amoxicillin allergy] |
| | Start Date: | UNK/UNK/2010 |
| | Ongoing: | YES |
| 1.b | Line/MH Number: | [2] |
| | Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies: | [premenarche] |
| | Start Date: | (b) (6) /2007 |
| | Ongoing: | YES |
| 1.c | Line/MH Number: | [3] |
| | Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies: | [vegetarian] |
| | Start Date: | UNK/UNK/2019 |
| | Ongoing: | YES |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: HIV STATUS

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[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: 10-Dec-2020 02:29

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Vital Signs

| | | |
|----|------------------|-------------|
| 1. | Date: | Dec/18/2020 |
| 2. | Weight: | [40.8] |
| 3. | Unit: | kg |
| 4. | Height: | [156.1] |
| 5. | Unit: | cm |
| 6. | Body Mass Index: | [16.7] |

Vital Signs Details

| | | |
|-----|-----------------------|-------------|
| 7.a | Record Identifier: | 1 |
| | Temperature: | [36.7] |
| | Unit: | C |
| | Temperature Location: | ORAL CAVITY |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:23

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Lab Urinalysis

| | | |
|----|---------------------------------------|--------------|
| 1. | Lab Panel: | URINALYSIS |
| 2. | Lab Sub-Panel: | PREGNANCY |
| 3. | Collection Date: | Dec/18/2020 |
| 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 |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Disposition

| | | |
|----|-----------------------|-------------|
| 1. | Randomization Date : | Dec/18/2020 |
| 2. | Randomization Number: | [23275] |
| 3. | Randomization Group: | [] |

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1039**Site Name:** (1039) ARC Clinical Research at Wilson Parke**Subject No:** 10391285**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Dec/18/2020 |
| 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 | [BS6HKS] |
| 5.b | Sample ID | [BRJBLY] |
| 5.c | Sample ID | [BRJBLZ] |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Dec/18/2020 |
| 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 | [BRJB6G] |
|-----|-----------|----------|

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:26

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Vaccination

| | | |
|-----|---|---|
| 1. | Was there a temporary delay of vaccination? | NO |
| 2. | Treatment Name | [BLINDED THERAPY] |
| 3. | Formulation: | INJECTION |
| 4. | Dose Date Time: | Dec/18/2020 09:59 |
| 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 |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Reactogenicity Diary

| | | |
|----|---|--|
| 1. | Select appropriate response - Reactogenicity diary collection | YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT |
|----|---|--|

Header Text: c4591001

Visit: V2_VAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

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

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

| | | |
|-----|---|----------|
| 1. | Were medications to treat fever/pain given on the last day the Subject Diary was completed? | NO |
| 2.a | Symptom: | FEVER |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.b | Symptom: | FATIGUE |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.c | Symptom: | HEADACHE |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | |
|-----|--|-------------------------------|
| 2.d | Symptom: | CHILLS |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.e | Symptom: | VOMITING |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.f | Symptom: | DIARRHEA |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.g | Symptom: | NEW OR WORSENERED MUSCLE PAIN |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.h | Symptom: | NEW OR WORSENERED JOINT PAIN |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | |
|-----|--|------------------------|
| 3. | Injection Site Location: | DELTOID MUSCLE |
| 4. | Injection Site Body Side: | LEFT |
| 5.a | Injection Site Reaction: | REDNESS |
| | Were injection site reactions present on the last day the Subject Diary was completed? | NO |
| 5.b | Injection Site Reaction: | SWELLING |
| | Were injection site reactions present on the last day the Subject Diary was completed? | NO |
| 5.c | Injection Site Reaction: | PAIN AT INJECTION SITE |
| | Were injection site reactions present on the last day the Subject Diary was completed? | NO |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:27

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Vital Signs

| | | |
|----|-------|------------|
| 1. | Date: | Jan/8/2021 |
|----|-------|------------|

Vital Signs Details

| | | |
|-----|-----------------------|-------------|
| 2.a | Record Identifier: | 1 |
| | Temperature: | [36.6] |
| | Unit: | C |
| | Temperature Location: | ORAL CAVITY |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 10-Dec-2020 02:23**Site No:** 1039**Subject No:** 10391285**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1039) ARC Clinical Research at Wilson Parke**Subject Initials:** ---**Generated Time (GMT):** 10-Nov-2021 20:44[Form Comments](#)[eCRF Audit Trail History](#)**Lab Urinalysis**

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

Lab Result

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

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BRJBB9] |
|-----|-----------|----------|

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Vaccination

| | | |
|-----|---|---|
| 1. | Was there a temporary delay of vaccination? | NO |
| 2. | Treatment Name | [BLINDED THERAPY] |
| 3. | Formulation: | INJECTION |
| 4. | Dose Date Time: | Jan/8/2021 08:51 |
| 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 |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

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

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

Site No: 1039 **Site Name:** (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

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

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Dec-2020 02:30 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1039 **Site Name:** (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

| | | |
|-----|---|----------|
| 1. | Were medications to treat fever/pain given on the last day the Subject Diary was completed? | NO |
| 2.a | Symptom: | FEVER |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.b | Symptom: | FATIGUE |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.c | Symptom: | HEADACHE |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Dec-2020 02:30 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1039 **Site Name:** (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

| | | |
|-----|--|-------------------------------|
| 2.d | Symptom: | CHILLS |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.e | Symptom: | VOMITING |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.f | Symptom: | DIARRHEA |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.g | Symptom: | NEW OR WORSENERED MUSCLE PAIN |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.h | Symptom: | NEW OR WORSENERED JOINT PAIN |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Dec-2020 02:30 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1039 **Site Name:** (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

| | | |
|-----|--|------------------------|
| 3. | Injection Site Location: | DELTOID MUSCLE |
| 4. | Injection Site Body Side: | LEFT |
| 5.a | Injection Site Reaction: | REDNESS |
| | Were injection site reactions present on the last day the Subject Diary was completed? | NO |
| 5.b | Injection Site Reaction: | SWELLING |
| | Were injection site reactions present on the last day the Subject Diary was completed? | NO |
| 5.c | Injection Site Reaction: | PAIN AT INJECTION SITE |
| | Were injection site reactions present on the last day the Subject Diary was completed? | NO |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

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:** 1039**Site Name:** (1039) ARC Clinical Research at Wilson Parke**Subject No:** 10391285**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BRGCCB] |
| 5.b | Sample ID | [BRGCCC] |
| 5.c | Sample ID | [BS6HG5] |

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

| Date of Visit | | | |
|---------------|-----------------|-------------------------------|--------------------------|
| 1. | Date of Visit | Not Applicable _____ // | Comments |
| 2. | Erroneous Visit | ERRONEOUS VISIT | |

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5-a | Sample ID | [BRGCKT] |
| 5-b | Sample ID | [BLBDNB] |
| 5-e | Sample ID | [BS6HTX] |
| 5-d | Sample ID | [BRMFT9] |
| 5-e | Sample ID | [BRGCKV] |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (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: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date of Visit

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

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Version: 30-Apr-2021 01:47

Form Status: Not Started

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Signs and Symptoms

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

Symptoms

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

Symptoms - Other

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

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (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: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 30-Apr-2021 01:37

Form Status: Not Started

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

| | | |
|----|--|--|
| 3. | Has the subject been hospitalized due to potential COVID-19 illness? | |
|----|--|--|

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (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: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date of Visit

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

COVID-19 Illness Visit

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

Header Text: c4591001**Visit:** POT_COVID_CONVA - New
Unscheduled Visit**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1039**Site Name:** (1039) ARC Clinical Research at Wilson
Parke**Subject No:** 10391285**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

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

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

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date of Visit

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

COVID-19 Repeat Swab

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

Header Text: c4591001**Visit:** POT_COVID_REPEAT_SWAB - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB**Form Version:** 10-Oct-2020 15:57 **Form Status:** Not Started**Site No:** 1039**Site Name:** (1039) ARC Clinical Research at Wilson Parke**Subject No:** 10391285**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled
Visit on Jul/26/2021

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Jul/26/2021 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled
Visit on Jul/26/2021

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Unplanned Assessments

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

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled
Visit on Jul/26/2021

Form: CONTACT OUTCOME - UNPLANNED

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Contact Outcome

| | | |
|----|-------------------|--|
| 1. | Contact Type: | TELEPHONE VISIT |
| 2. | Was contact made? | YES Date of Contact: Jul/26/2021 Contact Outcome: VISIT NOT REQUIRED, DATA ENTRY ERROR IN E-DIARY |
| 3. | Comments: | [] |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date of Visit

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VITAL SIGNS - TEMP

Form Version: 30-Apr-2021 01:41

Form Status: Not Started

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Vital Signs

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

Vital Signs Details

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

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

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:** 1039**Site Name:** (1039) ARC Clinical Research at Wilson
Parke**Subject No:** 10391285**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44**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: | |

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Vaccination

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

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (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: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Contact Outcome

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01

Form Status: Not Started

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Contact Outcome

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

Header Text: c4591001

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

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

Site No: 1039 **Site Name:** (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Mar/26/2021 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Informed Consent - Asymptomatic Surveillance

| | | |
|----|--------------|--|
| 1. | Consent Was: | OBTAINED Date Written Consent Obtained Mar/26/2021 |
|----|--------------|--|

Header Text: c4591001**Visit:** V201_SURVEIL_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING -
Unscheduled IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified**Site No:** 1039**Site Name:** (1039) ARC Clinical Research at Wilson
Parke**Subject No:** 10391285**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Mar/26/2021 |
| 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 | [BLBDNB] |
| 5.b | Sample ID | [BRGCKT] |
| 5.c | Sample ID | [BRGCKV] |

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Mar/26/2021 |
| 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 | [BRMFT9] |
|-----|-----------|----------|

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT

Form Version: 10-Dec-2020 02:29 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Disposition - Treatment

| | | |
|----|---|-------------|
| 1. | Date of Completion/Discontinuation /Death : | Feb/5/2021 |
| 2. | Phase of Disposition: | VACCINATION |
| 3. | Status: | COMPLETED |
| 4. | Specify Status: | [] |

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 -
Unscheduled Visit on Apr/09/2021

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|------------|
| 1. | Date of Visit | Apr/9/2021 |
| 2. | Erroneous Visit | |

COVID-19 Surveillance Visit

| | | |
|----|---------------------------------|-------------|
| 3. | COVID-19 Surveillance Visit: | SSWAB_WEEK2 |
|----|---------------------------------|-------------|

Header Text: c4591001**Visit:** V202_SURVEIL_SWAB 1 -
Unscheduled Visit on Apr/09/2021**Form Version:** 10-Oct-2020 15:57**Site No:** 1039**Subject No:** 10391285**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT
SWAB**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1039) ARC Clinical Research at Wilson
Parke**Subject Initials:** ---**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

| | | |
|----|--|--|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB_SELF |
| 3. | Sample Collected? | YES Date of Collection: Apr/9/2021 |
| 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 | [AA00171] |
|-----|-----------|-----------|

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 2 -
Unscheduled Visit on Apr/22/2021

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Apr/22/2021 |
| 2. | Erroneous Visit | |

COVID-19 Surveillance Visit

| | | |
|----|---------------------------------|-------------|
| 3. | COVID-19 Surveillance Visit: | SSWAB_WEEK4 |
|----|---------------------------------|-------------|

Header Text: c4591001**Visit:** V202_SURVEIL_SWAB 2 -
Unscheduled Visit on Apr/22/2021**Form Version:** 10-Oct-2020 15:57**Site No:** 1039**Subject No:** 10391285**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT
SWAB**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1039) ARC Clinical Research at Wilson
Parke**Subject Initials:** ---**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB_SELF |
| 3. | Sample Collected? | YES Date of Collection: Apr/22/2021 |
| 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 | [AA01236] |
|-----|-----------|-----------|

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 3 -
Unscheduled Visit on May/06/2021

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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Date of Visit

| | | |
|----|-----------------|------------|
| 1. | Date of Visit | May/6/2021 |
| 2. | Erroneous Visit | |

COVID-19 Surveillance Visit

| | | |
|----|---------------------------------|-------------|
| 3. | COVID-19 Surveillance Visit: | SSWAB_WEEK6 |
|----|---------------------------------|-------------|

Header Text: c4591001**Visit:** V202_SURVEIL_SWAB 3 -
Unscheduled Visit on May/06/2021**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT
SWAB**Form Version:** 10-Oct-2020 15:57**Form Status:** Data Complete, Frozen, Verified**Site No:** 1039**Site Name:** (1039) ARC Clinical Research at Wilson
Parke**Subject No:** 10391285**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

| | | |
|----|--|--|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB_SELF |
| 3. | Sample Collected? | YES Date of Collection: May/6/2021 |
| 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 | [AA00189] |
|-----|-----------|-----------|

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT
Unscheduled

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

Site No: 1039 **Site Name:** (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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| Date of Visit | | |
|---------------|-----------------|-------------|
| 1. | Date of Visit | May/12/2021 |
| 2. | Erroneous Visit | |

Header Text: c4591001

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

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

Site No: 1039 **Site Name:** (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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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: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Disposition - Follow-Up

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

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| # | Category | AE Identifier | Adverse Event | Start Date | Is the Adverse Event Still Ongoing | Form Instance |
|----|---------------|---------------|---------------------|-------------------|---|---------------------------------|
| 1. | ADVERSE EVENT | 1 | fatigue | May/14/2021 18:00 | NO End Date Time: May/15/2021 18:00 | Repeating Pages |
| 2. | ADVERSE EVENT | 2 | nausea | May/14/2021 18:00 | NO End Date Time: May/15/2021 18:00 | Repeating Pages |
| 3. | ADVERSE EVENT | 3 | injection site pain | May/15/2021 08:00 | NO End Date Time: May/15/2021 UNK:UNK | Repeating Pages |
| 4. | ADVERSE EVENT | 4 | fever | Jun/4/2021 14:00 | NO End Date Time: Jun/5/2021 UNK:UNK | Repeating Pages |
| 5. | ADVERSE EVENT | 5 | nausea | Jun/4/2021 14:00 | NO End Date Time: Jun/5/2021 UNK:UNK | Repeating Pages |

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Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| # | Category | AE Identifier | Adverse Event | Start Date | Is the Adverse Event Still Ongoing | Form Instance |
|----|---------------|---------------|------------------------|------------------|--|---------------------------------|
| 6. | ADVERSE EVENT | 6 | muscle aches | Jun/4/2021 14:00 | NO End Date Time: Jun/5/2021 UNK:UNK | Repeating Pages |
| 7. | ADVERSE EVENT | 7 | Generalized Arthralgia | Jun/4/2021 14:00 | NO End Date Time: Jun/5/2021 UNK:UNK | Repeating Pages |

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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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) | [fatigue] |
| 4. | Start Date Time: | May/14/2021 18:00 |
| 5. | Is the adverse event still ongoing? | NO End Date Time: May/15/2021 18:00 |
| 6. | Toxicity Grade: | 1 |

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

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Header Text: c4591001

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Form: ADVERSE EVENT REPORT

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Form Status: Data Complete, Frozen

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

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| | | |
|-----|--|--------------------|
| 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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Header Text: c4591001

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Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1039) ARC Clinical Research at Wilson Parke

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) | [nausea] |
| 4. | Start Date Time: | May/14/2021 18:00 |
| 5. | Is the adverse event still ongoing? | NO End Date Time: May/15/2021 18:00 |
| 6. | Toxicity Grade: | 1 |

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Header Text: c4591001

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Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | |
|-----|--|--------------------|
| 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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Subject No: 10391285

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

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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) | [injection site pain] |
| 4. | Start Date Time: | May/15/2021 08:00 |
| 5. | Is the adverse event still ongoing? | NO End Date Time: May/15/2021 UNK:UNK |
| 6. | Toxicity Grade: | 1 |

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Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

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

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Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

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| | | |
|-----|--|--------------------|
| 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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Adverse Event Report

| | | |
|----|--|--|
| 1. | Category: | ADVERSE EVENT |
| 2. | AE ID: | [4] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [fever] |
| 4. | Start Date Time: | Jun/4/2021 14:00 |
| 5. | Is the adverse event still ongoing? | NO End Date Time: Jun/5/2021 UNK:UNK |
| 6. | Toxicity Grade: | 1 |

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Subject No: 10391285

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Form Status: Data Complete, Frozen

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

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

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Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

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| | | |
|-----|--|--------------------|
| 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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Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

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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) | [nausea] |
| 4. | Start Date Time: | Jun/4/2021 14:00 |
| 5. | Is the adverse event still ongoing? | NO End Date Time: Jun/5/2021 UNK:UNK |
| 6. | Toxicity Grade: | 1 |

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Site No: 1039

Subject No: 10391285

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Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

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

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

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Form Status: Data Complete, Frozen

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

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| | | |
|-----|--|--------------------|
| 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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Subject Initials: ---

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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) | [muscle aches] |
| 4. | Start Date Time: | Jun/4/2021 14:00 |
| 5. | Is the adverse event still ongoing? | NO End Date Time: Jun/5/2021 UNK:UNK |
| 6. | Toxicity Grade: | 1 |

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Subject No: 10391285

Generated By: (b) (4)

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Site Name: (1039) ARC Clinical Research at Wilson Parke

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

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Header Text: c4591001

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Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

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| | | |
|-----|--|--------------------|
| 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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Header Text: c4591001

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Subject No: 10391285

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

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Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

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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) | [Generalized Arthralgia] |
| 4. | Start Date Time: | Jun/4/2021 14:00 |
| 5. | Is the adverse event still ongoing? | NO End Date Time: Jun/5/2021 UNK:UNK |
| 6. | Toxicity Grade: | 1 |

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Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

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

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

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

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| # | 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: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Form Status: Not Started

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Medication Error

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

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Concomitant Medications

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

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Concomitant Medications

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

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Radiation Treatment

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

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 10-Dec-2020 02:27

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Treatment Unblinded

| | | |
|----|--------------------------------|---|
| 1. | Date Treatment Unblinded : | May/12/2021 |
| 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: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Death Details

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

Cause of Death

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

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

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

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

| | | |
|----|--------------|--|
| 1. | Consent Was: | OBTAINED Date Written Consent Obtained May/14/2021 |
|----|--------------|--|

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 28-Mar-2021 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

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: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

| | | |
|----|---|--------------------|
| 1. | Date of Completion/Discontinuation /Death : | May/14/2021 |
| 2. | Phase of Disposition: | REPEAT SCREENING 1 |
| 3. | Status: | COMPLETED |
| 4. | Specify Status: | [] |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 30-Apr-2021 01:41

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Frozen, Verified

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Lab Urinalysis

| | | |
|----|---------------------------------------|--------------|
| 1. | Lab Panel: | URINALYSIS |
| 2. | Lab Sub-Panel: | PREGNANCY |
| 3. | Collection Date: | May/14/2021 |
| 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 |

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: May/14/2021 |
| 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 | [BRDP7D] |
| 5.b | Sample ID | [BRDP7F] |
| 5.c | Sample ID | [BLBDDDB] |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: May/14/2021 |
| 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 | [BRMFWG] |
|-----|-----------|----------|

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Vaccination

| | | |
|-----|---|-------------------|
| 1. | Was there a temporary delay of vaccination? | NO |
| 2. | Treatment Name | [BNT162b2] |
| 3. | Formulation: | INJECTION |
| 4. | Dose Date Time: | May/14/2021 08:35 |
| 5. | Anatomical Location: | DELTOID MUSCLE |
| 6. | Body Side: | LEFT |
| 7. | Route: | INTRAMUSCULAR |
| 8. | Actual Dose: | [30.0] |
| 9. | Unit: | ug |
| 10. | Timeframe Subject Was Observed | 30 MINUTES |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? | YES |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

| Date of Visit | | |
|---------------|-----------------|------------|
| 1. | Date of Visit | Jun/4/2021 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V102_VAX4

Form Version: 30-Apr-2021 01:41

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Frozen, Verified

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Lab Urinalysis

| | | |
|----|---------------------------------------|--------------|
| 1. | Lab Panel: | URINALYSIS |
| 2. | Lab Sub-Panel: | PREGNANCY |
| 3. | Collection Date: | Jun/4/2021 |
| 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 |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|--|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Jun/4/2021 |
| 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 | [BRMFXW] |
|-----|-----------|----------|

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Vaccination

| | | |
|-----|---|------------------|
| 1. | Was there a temporary delay of vaccination? | NO |
| 2. | Treatment Name | [BNT162b2] |
| 3. | Formulation: | INJECTION |
| 4. | Dose Date Time: | Jun/4/2021 08:16 |
| 5. | Anatomical Location: | DELTOID MUSCLE |
| 6. | Body Side: | LEFT |
| 7. | Route: | INTRAMUSCULAR |
| 8. | Actual Dose: | [30.0] |
| 9. | Unit: | ug |
| 10. | Timeframe Subject Was Observed | 30 MINUTES |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? | YES |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

| Date of Visit | | |
|---------------|-----------------|-------------|
| 1. | Date of Visit | Jul/12/2021 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Data Complete, Frozen, Verified

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Contact Outcome

| | | |
|----|-------------------|--|
| 1. | Contact Type: | TELEPHONE VISIT |
| 2. | Was contact made? | YES Date of Contact: Jul/12/2021 |
| 3. | Comments: | [] |

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Disposition - Treatment

| | | |
|----|--|----------------------|
| 1. | Date of Completion/Discontinuation/Death : | Jul/12/2021 |
| 2. | Phase of Disposition: | OPEN LABEL TREATMENT |
| 3. | Status: | COMPLETED |
| 4. | Specify Status: | [] |

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Subject Status

| | | |
|----|---------------------|------------|
| 1. | Subject Status | FOLLOW-UP |
| 2. | Subject Status Date | Feb/5/2021 |

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: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Audit Trail](#)

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

- CRF_Sign

| Name | Signature Meaning | Date | Type | Action |
|----------------|-------------------|--|------|--------|
| Gretchen Crook | Approved | Sep-01-2021 10:02:02 (UTC-06:00) Central Time (US & Canada) | BOOK | Signed |

Affidavit:

By my dated signature below, I, GretchenCrook, 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.

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Version: 10-Oct-2020 16:00

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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| Item | Date | User | Comment |
|------|--|-----------------------------------|----------------|
| Form | Dec-18-2020 13:36:49 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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| Item | Date | User | Comment |
|------|--|-----------------------------------|----------------|
| Form | Jan-08-2021 15:05:52 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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| Item | Date | User | Comment |
|------|--|-----------------------------------|----------------|
| 1 | Jan-08-2021 15:05:52 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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| Item | Date | User | Comment |
|------|--|---------------------|----------------|
| 2 | Jan-08-2021 15:05:52 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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| Item | Date | User | Comment |
|------|--|---------------------|----------------|
| 3 | Jan-08-2021 15:05:52 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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| Item | Date | User | Comment |
|------|--|-----------------------------------|----------------|
| 4 | Jan-08-2021 15:05:52 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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| Item | Date | User | Comment |
|------|--|-----------------------------------|----------------|
| 5 | Jan-08-2021 15:05:52 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Applicable |

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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| Item | Date | User | Comment |
|------|--|---------------------|----------------|
| 6.a | Jan-08-2021 15:05:52 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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| Item | Date | User | Comment |
|------|--|-----------------------------------|----------------|
| 6.a | Jan-08-2021 15:05:52 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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| Item | Date | User | Comment |
|------|--|-----------------------------------|----------------|
| 6.a | Jan-08-2021 15:05:52 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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| Item | Date | User | Comment |
|------|--|---------------------|----------------|
| 1 | Apr-22-2021 09:18:59 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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| Item | Date | User | Comment |
|------|--|-----------------------------------|--|
| 3 | Mar-30-2021 10:12:35 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Form level comment is not a radial option, and only a comment box populates. <hr/> Not Applicable |

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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| Item | Date | User | Comment |
|------|--|---------------------|----------------|
| 4 | Mar-30-2021 10:13:01 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

Form Version: 28-Mar-2021 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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| Item | Date | User | Comment |
|------|---|---------------------|----------------|
| Form | May-14-2021 10:04:38 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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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 |
|-------------------|----------------------|--|------|--------|
| Gretchen Crook | Approved | Sep-01-2021 10:02:02 (UTC-06:00) Central Time (US & Canada) | BOOK | Signed |

Affidavit:

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

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

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

| | | | | |
|---------|-----|--|--|---|
| (b) (6) | N/A | Mar-26-2021 10:21:01 (UTC-06:00) Central Time (US & Canada) | | Edit - All signatures invalidated |
|---------|-----|--|--|---|

Affidavit:

N/A

| | | | | |
|-------------------|----------|--|------|--------|
| Gretchen Crook | Approved | Mar-10-2021 14:46:57 (UTC-06:00) Central Time (US & Canada) | BOOK | Signed |
|-------------------|----------|--|------|--------|

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Status: Data Complete, Signed, Verified

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

Affidavit:

By my dated signature below, I, GretchenCrook, 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.

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Select appropriate response - Protocol version

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|-----------------------------------|---------------|
| Dec-18-2020 13:33:14 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: 01 DEC 2020 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|---------------------------------------|---------------|
| Dec-18-2020 13:33:14 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: STAGE 3 COHORTS | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Consent Was:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--|---------------|
| Dec-18-2020 13:33:45 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: OBTAINED Date Written Consent Obtained Dec/18/2020 | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Subject ID

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|--------------------------------|--------------------------------------|
| Dec-18-2020 13:32:23 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: 10391285 | Item copied from previous form |

2. Birth Date:

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|-------------------------------------|------------------|
| Dec-18-2020 13:31:50 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: (b) (6) /2007 | Enrollment Entry |

3. Sex:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|------------------------------|---------------|
| Dec-18-2020 13:34:08 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: FEMALE | Initial Entry |

4. Ethnicity:

| Date | Location | User | Value | Reason |
|-------------------------|-------------------|---------------------|---|---------------|
| Dec-18-2020 13:34:08 | ACV0PF EINFP60 | (b) (4), (b) (6) | Data Entry: NOT HISPANIC OR LATIN | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | |
|--|----|------------------|---------------------------|
| (UTC-06:00) Central Time (US & Canada) | 00 | (b) (4), (b) (6) | O(A) OR OF SPANISH ORIGIN |
|--|----|------------------|---------------------------|

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

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|-----------------------------|---------------|
| Dec-18-2020 13:34:08 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: WHITE | Initial Entry |

6. Racial Designation:

| Date | Location | User | Value | Reason |
|---|---|---------------------------|-------------------|--|
| Jan-21-2021 23:58:08 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Jan-21-2021 20:39:42 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00.InFor mAdapte r.Discrep ancy | DMW QUERY (b) (4) | Query 2: Closed | Auto closed by Validation Check: VC_DM001_09 |
| Jan-21-2021 13:34:06 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 2: Answered | Changed Information |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|---|---|---------------------------|-----------------------------|---|
| Jan-21-2021 13:34:06 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 1: Answered | Changed Information |
| Jan-21-2021 13:34:06 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: | Changed Information |
| Jan-21-2021 12:41:21 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00.InFormAdap ter.Discrepancy | DMW QUERY (b) (4) | Query 2: Opened | DMW6938339;Racial Designation is updated, however Race is not ASIAN. Please review and update appropriately or clarify. |
| Jan-21-2021 11:32:16 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00.InFormAdap ter.Discrepancy | DMW QUERY (b) (4) | Query 1: Opened | DMW6938339;Racial Designation is updated, however Race is not ASIAN. Please review and update appropriately or clarify. |
| Dec-18-2020 13:34:08 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: OTHER | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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1. Date of Visit

| Date | Location | User | Value | Reason |
|--|-------------------------|-----------------------------------|-----------------------------------|---------------|
| Dec-18-2020 13:36:11 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) [Redacted] | Data Entry: Dec/18/2020 | Initial Entry |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|-----------------------------------|---------------|
| Dec-18-2020 13:38:40 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Dec/18/2020 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|---------------------------------|---------------|
| Dec-18-2020 13:38:40 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: SCREENING | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|---------------------------------|---------------|
| Dec-18-2020 13:38:40 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1.a

| Date | Location | User | Value | Reason |
|---|-------------------------|-------------------------|--|---------------|
| Dec-18-2020 13:46:12 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: Line/MH Number: 1 Medical History Term: amoxicillin allergy Start Date: UNK/UNK/2010 Ongoing: YES | Initial Entry |

1.a Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-------------------------|-------------------------|-------------------------|---------------|
| Dec-18-2020 13:46:12 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: 1 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|---|---------------|
| Dec-18-2020 13:46:12 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: amoxicillin allergy | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

1.a Start Date:

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|------------------------------------|---------------|
| Dec-18-2020 13:46:12 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: UNK/UNK/2010 | Initial Entry |

1.a Ongoing:

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|---------------------------|---------------|
| Dec-18-2020 13:46:12 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

1.b

| Date | Location | User | Value | Reason |
|---|-------------------------|-------------------------|---|---------------|
| Dec-18-2020 13:49:49 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: Line/MH Number: Medical History Term: premenarche Start Date: (b) (6) 2007 Ongoing: YES | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

1.b Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-------------------------|-------------------------|-------------------------|---------------|
| Dec-18-2020 13:49:49 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: 2 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|-----------------------------------|---------------|
| Dec-18-2020 13:49:49 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: premenarche | Initial Entry |

1.b Start Date:

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|-------------------|--------------------------|
| Jan-13-2021 10:29:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Dec-30-2020 11:03:31 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Query 1: Answered | Changed data per query |
| Dec-23-2020 | ACV0PF | (b) (4), (b) (6) | Query 1: Opened | Please update |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|---|-------------------------|---------------------|-------------------------------------|--|
| 14:30:24 (UTC-06:00) Central Time (US & Canada) | EINFP60 00 | (b) (4), (b) (6) | | source documents to include start date as appropriate. |
| Dec-18-2020 13:49:49 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: (b) (6) /2007 | Initial Entry |

1.b Ongoing:

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|---------------------------|---------------|
| Dec-18-2020 13:49:49 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

1.c

| Date | Location | User | Value | Reason |
|---|-------------------------|-------------------------|---|---------------|
| Dec-18-2020 13:50:10 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: Line/MH Number: Medical History Term: vegetarian Start Date: UNK/UNK /2019 Ongoing: YES | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

I.c Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-------------------------|-------------------------|-------------------------|---------------|
| Dec-18-2020 13:50:10 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: 3 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|----------------------------------|---------------|
| Dec-18-2020 13:50:10 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: vegetarian | Initial Entry |

I.c Start Date:

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|------------------------------------|---------------|
| Dec-18-2020 13:50:10 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: UNK/UNK/2019 | Initial Entry |

I.c Ongoing:

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|---------------------------|---------------|
| Dec-18-2020 13:50:10 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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

| Date | Location | User | Value | Reason |
|--|-------------------------|-----------------------------------|--|---------------|
| Dec-18-2020 13:41:12 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) [REDACTED] | Data Entry: The subject is NOT known to be HIV POSITIVE | Initial Entry |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date:

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|-----------------------------------|---------------|
| Dec-18-2020 13:44:51 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Dec/18/2020 | Initial Entry |

2. Weight:

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|----------------------------|---------------|
| Dec-18-2020 13:44:51 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: 40.8 | Initial Entry |

3. Unit:

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--------------------------|---------------|
| Dec-18-2020 13:44:51 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: kg | Initial Entry |

4. Height:

| Date | Location | User | Value | Reason |
|-------------|----------|------------------|--------------------|---------------|
| Dec-18-2020 | ACV0PF | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|---|---------------|---------------------|-------|--|
| 13:44:51 (UTC-06:00) Central Time (US & Canada) | EINFP60 00 | (b) (4), (b) (6) | 156.1 | |
|---|---------------|---------------------|-------|--|

5. Unit:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------|---------------|
| Dec-18-2020 13:44:51 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: cm | Initial Entry |

6. Body Mass Index:

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|----------------------------|---------------|
| Dec-18-2020 13:44:51 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: 16.7 | Initial Entry |

7.a

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|---|---------------|
| Dec-18-2020 13:44:51 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Record Identifier: Temperature: 36.7 Temperature U C nit: Temperature L ORAL CA ocation:: VITY | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

7.a Record Identifier:

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|-------------------------|---------------|
| Dec-18-2020 13:44:51 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

7.a Temperature:

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|----------------------------|---------------|
| Dec-18-2020 13:44:51 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: 36.7 | Initial Entry |

7.a Unit:

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|-------------------------|---------------|
| Dec-18-2020 13:44:51 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: C | Initial Entry |

7.a Temperature Location:

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|-----------------------------------|---------------|
| Dec-18-2020 13:44:51 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: ORAL CAVITY | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Lab Panel:

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|----------------------------------|---------------|
| Dec-18-2020 13:44:21 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: URINALYSIS | Initial Entry |

2. Lab Sub-Panel:

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|---------------------------------|---------------|
| Dec-18-2020 13:44:21 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: PREGNANCY | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|--|-------------------------|-----------------------------------|-----------------------------------|---------------|
| Dec-18-2020 13:44:21 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) [REDACTED] | Data Entry: Dec/18/2020 | Initial Entry |

4. Laboratory Name and Address (Derived)

| Date | Location | User | Value | Reason |
|-------------|----------|-----------|--------------------|---------------|
| Dec-18-2020 | ACV0PF | auto calc | Data Entry: | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|---|---------------|------------|------------|--|
| 13:44:21 (UTC-06:00) Central Time (US & Canada) | EINFP60 00 | (autocalc) | STUDY SITE | |
|---|---------------|------------|------------|--|

5. Specimen Type:

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|-----------------------------|---------------|
| Dec-18-2020 13:44:21 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: URINE | Initial Entry |

6.a

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|--|---------------|
| Dec-18-2020 13:44:21 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: Sponsor-Def 113 ined Identifi er: Test:: Choriogonadot ropin Beta_PX 113 Result:: Not Done:: NOT DONE | Initial Entry |

6.a Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|---------------------------|---------------|
| Dec-18-2020 13:44:21 (UTC-06:00) Central | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: 113 | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Time (US & Canada)

6.a Test:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|---|---------------|
| Dec-18-2020 13:44:21 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Choriogonadotropin Beta_P X113 | Initial Entry |

6.a Not Done:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------------|---------------|
| Dec-18-2020 13:44:21 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NOT DONE | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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1. Randomization Date :

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|-----------------------------------|---------------|
| Dec-18-2020 13:45:16 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Dec/18/2020 | Initial Entry |

2. Randomization Number:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|-----------------------------|---------------|
| Dec-18-2020 13:45:16 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: 23275 | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (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: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-------------------------|-------------------------|----------------------------|---------------|
| Dec-18-2020 13:41:47 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-------------------------|-------------------------|-----------------------------|---------------|
| Dec-18-2020 13:41:47 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------------|--------------------|---|
| Dec-18-2020 17:02:11 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Dec-18-2020 13:41:47 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (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: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|---|-------------------------|---------------------|---|------------------------------------|
| | | | | review and correct as appropriate. |
| Dec-18-2020 13:41:47 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Dec/18/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-------------------------|------------------|--|---------------|
| Dec-18-2020 17:02:11 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Sample ID: BS6HKS | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-------------------------|------------------|------------------------------|---------------|
| Dec-18-2020 17:02:11 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: BS6HKS | Initial Entry |

5.b

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

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (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: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|---|-------------------------|---------------------|--|---------------|
| Dec-18-2020 17:02:18 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Sample ID: BRJBLY | Initial Entry |
|---|-------------------------|---------------------|--|---------------|

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|------------------------------|---------------|
| Dec-18-2020 17:02:18 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: BRJBLY | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--|---------------|
| Dec-18-2020 17:02:23 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Sample ID: BRJBLZ | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (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: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

5.c Sample ID

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|------------------------------|---------------|
| Dec-18-2020 17:02:23 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: BRJBLZ | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|----------------------------|---------------|
| Dec-18-2020 13:43:59 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|----------------------------------|---------------|
| Dec-18-2020 13:43:59 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------------|--------------------|---|
| Dec-18-2020 17:22:20 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Dec-18-2020 13:43:59 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|---|-------------------------|---------------------|---|------------------------------------|
| | | | | review and correct as appropriate. |
| Dec-18-2020 13:43:59 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Dec/18/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--|---------------|
| Dec-18-2020 17:22:20 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Sample ID: BRJB6G | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|------------------------------|---------------|
| Dec-18-2020 17:22:20 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: BRJB6G | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:26

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--------------------------|---------------|
| Dec-18-2020 13:45:38 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2. Treatment Name

| Date | Location | User | Value | Reason |
|---|-------------------------|-------------------------|---------------------------------------|---------------|
| Dec-18-2020 13:45:38 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: BLINDED THERAPY | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|---|-------------------------|-------------------------|---------------------------------|---------------|
| Dec-18-2020 13:45:38 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: INJECTION | Initial Entry |

4. Dose Date Time:

| Date | Location | User | Value | Reason |
|-------------------------|-------------------|---------------------|---|---------------|
| Dec-18-2020 13:45:38 | ACV0PF EINFP60 | (b) (4), (b) (6) | Data Entry: Dec/18/2020 09:59 | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|--|----|------------------|--|--|
| (UTC-06:00) Central Time (US & Canada) | 00 | (b) (4), (b) (6) | | |
|--|----|------------------|--|--|

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|---|-------------------------|-------------------------|--------------------------------------|---------------|
| Dec-18-2020 13:45:38 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|----------------------------|---------------|
| Dec-18-2020 13:45:38 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: LEFT | Initial Entry |

7. Route:

| Date | Location | User | Value | Reason |
|---|-------------------------|-------------------------|-------------------------------------|---------------|
| Dec-18-2020 13:45:38 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|-------------------------|-------------------|-------------------------|---|---------------|
| Dec-18-2020 13:45:38 | ACV0PF EINFP60 | auto calc (autocalc) | Data Entry: THE PROTOCOL SPECIFIE | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|--|----|--|----------------------|--|
| (UTC-06:00) Central Time (US & Canada) | 00 | | D OBSERVATION PERIOD | |
|--|----|--|----------------------|--|

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

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|---------------------------|--|
| Jan-13-2021 10:30:08 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Dec-30-2020 11:05:28 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Query 1: Answered | Changed data per query |
| Dec-23-2020 14:02:03 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Query 1: Opened | Please reconcile source documents with beginning of surveillance time and update as appropriate. |
| Dec-18-2020 13:45:38 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Select appropriate response - Reactogenicity diary collection

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--|---------------|
| Dec-18-2020 13:41:34 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: YES - REACTOGENICITY E-DIARY COLLECTED F OR THIS SUBJECT | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|----------------------------------|---|
| Jan-13-2021 10:30:36 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Jan-12-2021 12:20:16 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Query 1: Answered | Changed data per query |
| Jan-12-2021 10:21:24 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Query 1: Opened | Please provide source documents in Florence. |
| Jan-08-2021 15:05:12 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Jan/8/2021 | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--------------------------|---------------|
| Jan-08-2021 15:07:30 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--|---------------|
| Jan-08-2021 15:07:30 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Symptom:: FE V E R Were fever or systemi N c symptoms present o O n the last day the Subj ect Diary was complet ed?: | Initial Entry |

2.a Symptom:

| Date | Location | User | Value | Reason |
|-------------------------|-------------------|---------------------|-----------------------------|---------------|
| Jan-08-2021 15:07:30 | ACV0PF EINFP60 | (b) (4), (b) (6) | Data Entry: FEVER | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|--|----|------------------|--|--|
| (UTC-06:00) Central Time (US & Canada) | 00 | (b) (4), (b) (6) | | |
|--|----|------------------|--|--|

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-------------------|------------------|--------------------------|---------------|
| Jan-08-2021 15:07:30 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.b

| Date | Location | User | Value | Reason |
|---|-------------------|------------------|---|---------------|
| Jan-08-2021 15:07:30 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Symptom:: FA TI GU E Were fever or systemi c symptoms present o n the last day the Sub ject Diary was compl eted?: NO | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.b Symptom:

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|-------------------------------|---------------|
| Jan-08-2021 15:07:30 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: FATIGUE | Initial Entry |

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--------------------------|---------------|
| Jan-08-2021 15:07:30 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.c

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|---|---------------|
| Jan-08-2021 15:07:30 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Symptom:: HE AD AC HE Were fever or system NO ic symptoms present on the last day the S ubject Diary was co mpleted?: | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.c Symptom:

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--------------------------------|---------------|
| Jan-08-2021 15:07:30 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: HEADACHE | Initial Entry |

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--------------------------|---------------|
| Jan-08-2021 15:07:30 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.d

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--|---------------|
| Jan-08-2021 15:07:30 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Symptom:: C HI LL S Were fever or systemi N c symptoms present o O n the last day the Sub ject Diary was comple ted?: | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.d Symptom:

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|------------------------------|---------------|
| Jan-08-2021 15:07:30 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: CHILLS | Initial Entry |

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--------------------------|---------------|
| Jan-08-2021 15:07:30 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.e

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|---|---------------|
| Jan-08-2021 15:07:30 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Symptom:: VO MI TIN G Were fever or system NO ic symptoms present on the last day the S ubject Diary was co mpleted?: | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.e Symptom:

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--------------------------------|---------------|
| Jan-08-2021 15:07:30 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: VOMITING | Initial Entry |

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--------------------------|---------------|
| Jan-08-2021 15:07:30 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.f

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|---|---------------|
| Jan-08-2021 15:07:30 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Symptom:: DI AR RH EA Were fever or system NO ic symptoms present on the last day the Su bject Diary was com pleted?: | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.f Symptom:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------------|---------------|
| Jan-08-2021 15:07:30 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: DIARRHEA | Initial Entry |

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------|---------------|
| Jan-08-2021 15:07:30 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.g

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|---|---------------|
| Jan-08-2021 15:07:30 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Symptom:: NEW O R WOR SENED MUSCL E PAIN | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|--|--|--|--|--|
| | | | Were fever or sy NO stemic symptom s present on the l ast day the Subj ect Diary was co mpleted?: | |
|--|--|--|--|--|

2.g Symptom:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--|---------------|
| Jan-08-2021 15:07:30 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NEW OR WORSENE M USCLE PAIN | Initial Entry |

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------|---------------|
| Jan-08-2021 15:07:30 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.h

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|---|---------------|
| Jan-08-2021 15:07:30 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Symptom:: NEW O R WOR SENE D | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|--|--|--|---|--|
| | | | JOINT PAIN | |
| | | | Were fever or systemic symptoms present on the last day the Subject Diary was completed?: | |

2.h Symptom:

| Date | Location | User | Value | Reason |
|---|-------------------|------------------|--|---------------|
| Jan-08-2021 15:07:30 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NEW OR WORSEMENT PAIN | Initial Entry |

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-------------------|------------------|-----------------------|---------------|
| Jan-08-2021 15:07:30 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

3. Injection Site Location:

| Date | Location | User | Value | Reason |
|--|----------------|----------------------|-----------------------------------|---------------|
| Jan-08-2021 15:07:30 (UTC-06:00) Central | ACV0PF EINFP60 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|--------------------|----|--|--|--|
| Time (US & Canada) | 00 | | | |
|--------------------|----|--|--|--|

4. Injection Site Body Side:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|----------------------------|---------------|
| Jan-08-2021 15:07:30 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: LEFT | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--|---------------|
| Jan-08-2021 15:07:30 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Injection Site Reaction: RE DN ES S Were injection site reactions present on the last day the Subject Diary was completed?: NO | Initial Entry |

5.a Injection Site Reaction:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|-------------------------------|---------------|
| Jan-08-2021 15:07:30 (UTC-06:00) Central | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: REDNESS | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Time (US & Canada)

5.a Were injection site reactions present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------|---------------|
| Jan-08-2021 15:07:30 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|---|---------------|
| Jan-08-2021 15:07:30 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Injection Site Reaction: SW ELL ING Were injection site reactions present on the last day the Subject Diary was completed?: NO | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

5.b Injection Site Reaction:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------------|---------------|
| Jan-08-2021 15:07:30 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: SWELLING | Initial Entry |

5.b Were injection site reactions present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------|---------------|
| Jan-08-2021 15:07:30 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|---|---------------|
| Jan-08-2021 15:07:30 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Injection Site Rea PAIN ction:: AT IN JECTI ON SI TE Were injection site NO reactions present on the last day the Subject Diary was completed?: | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

5.c Injection Site Reaction:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--|---------------|
| Jan-08-2021 15:07:30 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: PAIN AT INJECTION SITE | Initial Entry |

5.c Were injection site reactions present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------|---------------|
| Jan-08-2021 15:07:30 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:27

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date:

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|----------------------------------|---------------|
| Jan-08-2021 15:05:29 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Jan/8/2021 | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--|---------------|
| Jan-08-2021 15:05:29 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Record Identifier:: Temperature: 36.6 Temperature U C nit: Temperature L ORAL CA ocation:: VITY | Initial Entry |

2.a Record Identifier:

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|-------------------------|---------------|
| Jan-08-2021 15:05:29 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

2.a Temperature:

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| Date | Location | User | Value | Reason |
|--|-------------------------|-----------------------------------|----------------------------|---------------|
| Jan-08-2021 15:05:29 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) [REDACTED] | Data Entry: 36.6 | Initial Entry |

2.a Unit:

| Date | Location | User | Value | Reason |
|--|-------------------------|-----------------------------------|-------------------------|---------------|
| Jan-08-2021 15:05:29 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) [REDACTED] | Data Entry: C | Initial Entry |

2.a Temperature Location:

| Date | Location | User | Value | Reason |
|--|-------------------------|-----------------------------------|-----------------------------------|---------------|
| Jan-08-2021 15:05:29 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) [REDACTED] | Data Entry: ORAL CAVITY | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Lab Panel:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------------------|---------------|
| Jan-08-2021 15:05:52 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2. Lab Sub-Panel:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------------------|---------------|
| Jan-08-2021 15:05:52 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------------------|---------------|
| Jan-08-2021 15:05:52 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

4. Laboratory Name and Address (Derived)

| Date | Location | User | Value | Reason |
|-------------|----------|------------------|--------------------|---------------|
| Jan-08-2021 | ACV0PF | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|---|---------------|---------------------|----------------|--|
| 15:05:52 (UTC-06:00) Central Time (US & Canada) | EINFP60 00 | (b) (4), (b) (6) | Not Applicable | |
|---|---------------|---------------------|----------------|--|

5. Specimen Type:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------------------|---------------|
| Jan-08-2021 15:05:52 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

6.a

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--|---------------|
| Jan-08-2021 15:05:52 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Sponsor-Define d Identifier: Not Appl icable Test:: Not Appl icable Result:: Not Appl icable Not Done:: Not Appl icable | Initial Entry |

6.a Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------------------|---------------|
| Jan-08-2021 15:05:52 (UTC-06:00) Central | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

6.a Test:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------------------|---------------|
| Jan-08-2021 15:05:52 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

6.a Result:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------------------|---------------|
| Jan-08-2021 15:05:52 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

6.a Not Done:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------------------|---------------|
| Jan-08-2021 15:05:52 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Data Origin

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|----------------------------|---------------|
| Jan-08-2021 15:07:40 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|----------------------------------|---------------|
| Jan-08-2021 15:07:40 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------------|--------------------|--|
| Jan-08-2021 16:19:03 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Jan-08-2021 15:07:40 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|---|-------------------------|---------------------|--|-------------------------|
| | | | | correct as appropriate. |
| Jan-08-2021 15:07:40 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Jan/8/2021 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--|---------------|
| Jan-08-2021 16:19:03 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Sample ID: BRJBB9 | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|------------------------------|---------------|
| Jan-08-2021 16:19:03 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: BRJBB9 | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------|---------------|
| Jan-08-2021 15:06:46 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2. Treatment Name

| Date | Location | User | Value | Reason |
|---|-------------------------|-------------------------|---------------------------------------|---------------|
| Jan-08-2021 15:06:46 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: BLINDED THERAPY | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|---|-------------------------|-------------------------|---------------------------------|---------------|
| Jan-08-2021 15:06:46 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: INJECTION | Initial Entry |

4. Dose Date Time:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--|---------------|
| Jan-08-2021 15:06:46 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Jan/8/2021 08:51 | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|--------------------------------------|---------------|
| Jan-08-2021 15:06:46 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|----------------------------|---------------|
| Jan-08-2021 15:06:46 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: LEFT | Initial Entry |

7. Route:

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|-------------------------------------|---------------|
| Jan-08-2021 15:06:46 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|---|---------------|
| Jan-08-2021 15:06:46 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: THE PROTOCOL SPECIFIE D OBSERVATION PERIOD | Initial Entry |

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

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| Date | Location | User | Value | Reason |
|--|-------------------------|-----------------------------------|---------------------------|---------------|
| Jan-08-2021 15:06:46 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) [Redacted] | Data Entry: YES | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT - eCRF Audit Trail History

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

Site No: 1039 **Site Name:** (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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1. Date of Visit

| Date | Location | User | Value | Reason |
|--|-------------------------|-----------------------------------|----------------------------------|---------------|
| Feb-05-2021 10:26:53 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) [REDACTED] | Data Entry: Feb/5/2021 | Initial Entry |

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1039 **Site Name:** (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--------------------------|---------------|
| Feb-05-2021 10:27:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--|---------------|
| Feb-05-2021 10:27:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Symptom:: FE V ER Were fever or systemi N c symptoms present o O n the last day the Subj ect Diary was complet ed?: | Initial Entry |

2.a Symptom:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|-----------------------------|---------------|
| Feb-05-2021 10:27:19 (UTC-06:00) Central | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: FEVER | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1039 **Site Name:** (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

Time (US & Canada)

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------|---------------|
| Feb-05-2021 10:27:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.b

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|---|---------------|
| Feb-05-2021 10:27:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Symptom:: FA TI GU E Were fever or systemi NO c symptoms present o n the last day the Sub ject Diary was comple ted?: | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039 Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

2.b Symptom:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|-------------------------------|---------------|
| Feb-05-2021 10:27:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: FATIGUE | Initial Entry |

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------|---------------|
| Feb-05-2021 10:27:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.c

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|---|---------------|
| Feb-05-2021 10:27:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Symptom:: HE AD AC HE Were fever or system ic symptoms present on the last day the Su bject Diary was com pleted?: NO | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039 Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

2.c Symptom:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------------|---------------|
| Feb-05-2021 10:27:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: HEADACHE | Initial Entry |

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------|---------------|
| Feb-05-2021 10:27:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.d

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--|---------------|
| Feb-05-2021 10:27:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Symptom:: C HI LL S Were fever or systemi N c symptoms present o O n the last day the Subj ect Diary was complet ed?: | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039 Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

2.d Symptom:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|------------------------------|---------------|
| Feb-05-2021 10:27:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: CHILLS | Initial Entry |

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------|---------------|
| Feb-05-2021 10:27:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.e

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|---|---------------|
| Feb-05-2021 10:27:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Symptom:: VO MI TIN G Were fever or system NO ic symptoms present on the last day the Su bject Diary was com pleted?: | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039 Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

2.e Symptom:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------------|---------------|
| Feb-05-2021 10:27:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: VOMITING | Initial Entry |

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------|---------------|
| Feb-05-2021 10:27:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.f

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--|---------------|
| Feb-05-2021 10:27:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Symptom:: DI AR RH EA Were fever or systemi c symptoms present o n the last day the Sub ject Diary was compl eted?: NO | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039 Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

2.f Symptom:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------------|---------------|
| Feb-05-2021 10:27:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: DIARRHEA | Initial Entry |

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------|---------------|
| Feb-05-2021 10:27:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.g

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|---|---------------|
| Feb-05-2021 10:27:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Symptom:: NEW O R WOR SENED MUSCL E PAIN | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1039 **Site Name:** (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

| | | | | |
|--|--|--|---|--|
| | | | Were fever or systemic symptoms present on the last day the Subject Diary was completed?: | |
|--|--|--|---|--|

2.g Symptom:

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|---|---------------|
| Feb-05-2021 10:27:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NEW OR WORSENERED MUSCLE PAIN | Initial Entry |

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--------------------------|---------------|
| Feb-05-2021 10:27:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.h

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--|---------------|
| Feb-05-2021 10:27:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Symptom:: NEW OR WORSENERED | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039 Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|--|--|--|---|----|
| | | | JOINT PAIN | |
| | | | Were fever or systemic symptoms present on the last day the Subject Diary was completed?: | NO |

2.h Symptom:

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--|---------------|
| Feb-05-2021 10:27:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | <u>Data Entry:</u> NEW OR WORSENER JOINT PAIN | Initial Entry |

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--------------------------|---------------|
| Feb-05-2021 10:27:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

3. Injection Site Location:

| Date | Location | User | Value | Reason |
|-------------------------|-------------------|-------------------------|--------------------------------------|---------------|
| Feb-05-2021 10:27:19 | ACV0PF EINFP60 | auto calc (autocalc) | <u>Data Entry:</u> DELTOID MUSCLE | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039 Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

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

4. Injection Site Body Side:

| Date | Location | User | Value | Reason |
|---|-------------------|------------------|----------------------------|---------------|
| Feb-05-2021 10:27:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: LEFT | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-------------------|------------------|--|---------------|
| Feb-05-2021 10:27:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Injection Site Reaction: RE DN ES S Were injection site reactions present on the last day the Subject Diary was completed?: NO | Initial Entry |

5.a Injection Site Reaction:

| Date | Location | User | Value | Reason |
|--|-------------------|------------------|-------------------------------|---------------|
| Feb-05-2021 10:27:19 (UTC-06:00) Central | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: REDNESS | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1039 **Site Name:** (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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

5.a Were injection site reactions present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|--|-------------------------|-----------------------------------|--------------------------|---------------|
| Feb-05-2021 10:27:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) [REDACTED] | Data Entry: NO | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|--|-------------------------|-----------------------------------|--|---------------|
| Feb-05-2021 10:27:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) [REDACTED] | Data Entry: Injection Site Reactions: SW ELL ING Were injection site reactions present on the last day the Subject Diary was completed?: NO | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1039 Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

5.b Injection Site Reaction:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------------|---------------|
| Feb-05-2021 10:27:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: SWELLING | Initial Entry |

5.b Were injection site reactions present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------|---------------|
| Feb-05-2021 10:27:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--|---------------|
| Feb-05-2021 10:27:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Injection Site Reaction:: PAIN AT IN JECTI ON SI TE Were injection site reactions present o n the last day the S ubject Diary was c ompleted?: | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:30 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1039 **Site Name:** (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

5.c Injection Site Reaction:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--|---------------|
| Feb-05-2021 10:27:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: PAIN AT INJECTION SITE | Initial Entry |

5.c Were injection site reactions present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------|---------------|
| Feb-05-2021 10:27:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

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

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

Site No: 1039 **Site Name:** (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[Back to Form](#)

1. Data Origin

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|----------------------------|---------------|
| Feb-05-2021 10:27:51 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|-----------------------------|---------------|
| Feb-05-2021 10:27:51 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------------|--------------------|---|
| Feb-05-2021 14:09:35 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Feb-05-2021 10:27:51 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

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

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

Site No: 1039 Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|---|-------------------------|---------------------|--|------------------------------------|
| | | | | review and correct as appropriate. |
| Feb-05-2021 10:27:51 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Feb/5/2021 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-------------------------|------------------|--|---------------------|
| Feb-05-2021 14:10:24 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Sample ID: BRGCCB | Transcription Error |
| Feb-05-2021 14:09:35 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Sample ID: brgccb | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------------|------------------------------|---------------------|
| Feb-05-2021 14:10:24 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Feb-05-2021 14:10:24 | ACV0PF EINFP60 | (b) (4), (b) (6) | Data Entry: BRGCCB | Transcription Error |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

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

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

Site No: 1039 **Site Name:** (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

| | | | | |
|---|-------------------------|------------------------|------------------------------|--|
| (UTC-06:00) Central Time (US & Canada) | 00 | | | |
| Feb-05-2021 14:09:35 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 1: Opened | Barcode contains lower case letters which is not the correct format. Please review and correct as appropriate. |
| Feb-05-2021 14:09:35 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: brgccb | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-------------------------|------------------|--|---------------------|
| Feb-05-2021 14:11:11 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Sample ID: BRGCCC | Transcription Error |
| Feb-05-2021 14:10:43 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Sample ID: brgccc | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

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

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

Site No: 1039 Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

5.b Sample ID

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------------|------------------------------|---|
| Feb-05-2021 14:11:11 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Feb-05-2021 14:11:11 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: BRGCCC | Transcription Error |
| Feb-05-2021 14:10:43 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 1: Opened | Barcode contains lower case letters which is not the correct format. Please review and correct as appropriate. |
| Feb-05-2021 14:10:43 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: brgccc | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--|---------------|
| Feb-05-2021 14:18:41 (UTC-06:00) Central | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Sample ID: BS6HG5 | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

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

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

Site No: 1039 **Site Name:** (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

Time (US & Canada)

5.c Sample ID

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|------------------------------|---------------|
| Feb-05-2021 14:18:41 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: BS6HG5 | Initial Entry |

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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1. Date of Visit

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------------------|---------------|
| Apr-22-2021 09:18:59 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2. Erroneous Visit

| Date | Location | User | Value | Reason |
|--|-------------------------|------------------------|---------------------------------------|---------------|
| Mar-26-2021 13:42:20 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: ERRONEOUS VISIT | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-------------------------|-------------------------|----------------------------|---------------------|
| Mar-30-2021 10:11:15 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: | Changed Information |
| Mar-26-2021 13:28:54 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-------------------------|-------------------------|-----------------------------|---------------------|
| Mar-30-2021 10:11:15 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: | Changed Information |
| Mar-26-2021 13:28:54 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

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

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|--|-------------------------|---------------------------|--------------------------------------|--|
| Mar-31-2021 07:21:52 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Query 2: Closed | Response satisfies query |
| Mar-30-2021 10:12:35 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |
| Mar-30-2021 10:11:15 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 2: Answered | Answer Auto Query |
| Mar-30-2021 10:11:15 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: | Changed Information |
| Mar-30-2021 00:25:07 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Query 2: Reissued:Opened | DM1: Form level comment is still missing on this form. Kindly consider to erase the data from this form and then add form level comment by |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|--|-------------------------|------------------------|--------------------------|--|
| | | | | selecting Not Done or Not Applicable option on this form or else clarify. |
| Mar-29-2021 07:14:41 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Query 2: Answered | N/A |
| Mar-29-2021 03:05:14 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Query 2: Reissued:Opened | DM: If entered in error, please consider adding form level 'Not applicable' comment on this form. Thank you. |
| Mar-26-2021 13:53:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Query 2: Answered | The samples were inputted in the wrong visit. It was supposed to be in V201 and not V4 |
| Mar-26-2021 13:44:18 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 7: Closed | Close Auto Query |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|--|-------------------------|---------------------------|-----------------|--|
| Mar-26-2021 13:44:05 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 7: Opened | Response to "Sample Collected?" is No, but Barcodes are present on the page. |
| Mar-26-2021 13:44:05 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 6: Closed | Close Auto Query |
| Mar-26-2021 13:43:52 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 6: Opened | Response to "Sample Collected?" is No, but Barcodes are present on the page. |
| Mar-26-2021 13:43:52 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 5: Closed | Close Auto Query |
| Mar-26-2021 13:43:39 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 5: Opened | Response to "Sample Collected?" is No, but Barcodes are present on the |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|--|-------------------------|---------------------------|-----------------|--|
| | | | | page. |
| Mar-26-2021 13:43:39 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 4: Closed | Close Auto Query |
| Mar-26-2021 13:43:24 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 4: Opened | Response to "Sample Collected?" is No, but Barcodes are present on the page. |
| Mar-26-2021 13:43:24 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 3: Closed | Close Auto Query |
| Mar-26-2021 13:42:47 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 3: Opened | Response to "Sample Collected?" is No, but Barcodes are present on the page. |
| Mar-26-2021 13:42:47 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 2: Opened | 'Sample Collected?' is marked as No and 'If no sample was |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|--|-------------------------|---------------------------|---------------------------|--|
| | | | | collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate. |
| Mar-26-2021 13:42:47 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Transcription Error |
| Mar-26-2021 13:29:36 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Mar-26-2021 13:28:54 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Mar-26-2021 13:28:54 | ACV0PF EINFP60 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|--|----|--|--|--|
| (UTC-06:00) Central Time (US & Canada) | 00 | | Date of Collection: Mar/26/2021 | |
|--|----|--|--|--|

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------------------|---------------|
| Mar-30-2021 10:13:01 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--|--|
| Mar-26-2021 13:43:24 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Sample ID: BRGCKT | Transcription Error (DELETED) |
| Mar-26-2021 13:29:36 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Sample ID: BRGCKT | Initial Entry |

5.a Sample ID

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

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|---|-------------------------|---------------------|---|----------------------------------|
| Mar-26-2021 13:43:24 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: BRGCKT | Transcription Error (DELETED) |
| Mar-26-2021 13:29:36 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: BRGCKT | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--|----------------------------------|
| Mar-26-2021 13:43:39 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Sample ID: BLBDNB | Transcription Error (DELETED) |
| Mar-26-2021 13:29:52 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Sample ID: BLBDNB | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|------------------------------|--|
| Mar-26-2021 13:43:39 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: BLBDNB | Transcription Error (DELETED) |
| Mar-26-2021 13:29:52 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: BLBDNB | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--|--|
| Mar-26-2021 13:43:52 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Sample ID: BS6HTX | Transcription Error (DELETED) |
| Mar-26-2021 13:30:07 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Sample ID: BS6HTX | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

5.c Sample ID

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|------------------------------|----------------------------------|
| Mar-26-2021 13:43:52 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: BS6HTX | Transcription Error (DELETED) |
| Mar-26-2021 13:30:07 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: BS6HTX | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|---|----------------------------------|
| Mar-26-2021 13:44:05 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Sample ID: BRMET9 | Transcription Error (DELETED) |
| Mar-26-2021 13:30:27 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Sample ID: BRMFT9 | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

5.d Sample ID

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|-------------------------------------|--|
| Mar-26-2021 13:44:05 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: BRMFT9 | Transcription Error (DELETED) |
| Mar-26-2021 13:30:27 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: BRMFT9 | Initial Entry |

5.e

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--|--|
| Mar-26-2021 13:44:18 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Sample ID: BRGCKV | Transcription Error (DELETED) |
| Mar-26-2021 13:34:13 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Sample ID: BRGCKV | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

5.e Sample ID

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|---|--|
| Mar-26-2021 13:44:18 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: BRGCKV | Transcription Error (DELETED) |
| Mar-26-2021 13:34:13 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: BRGCKV | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled
Visit on Jul/26/2021

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|-----------------------------------|---------------|
| Jul-26-2021 14:13:42 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Jul/26/2021 | Initial Entry |

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Jul/26/2021

Form: UNPLANNED VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Assessments

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------------|---------------------------------------|--|
| Jul-26-2021 14:14:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Jul-26-2021 14:13:51 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 1: Candidate | 'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate. |
| Jul-26-2021 14:13:51 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: CONTACT OUTCOME | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Jul/26/2021

Form Version: 22-Apr-2020 21:04

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Contact Type:

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|---------------------------------------|---------------|
| Jul-26-2021 14:14:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: TELEPHONE VISIT | Initial Entry |

2. Was contact made?

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|---|---------------|
| Jul-26-2021 14:14:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: YES Date of Contact: Jul/26/2021 Contact Outcome: VISIT NOT REQUIRED, DATA ENTRY ERROR IN E-DIARY | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - **Form:** DATE OF VISIT - eCRF Audit Trail History
Unscheduled

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

Site No: 1039 **Site Name:** (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Visit

| Date | Location | User | Value | Reason |
|--|-------------------------|-----------------------------------|-----------------------------------|---------------|
| Mar-26-2021 10:21:01 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) [REDACTED] | <u>Data Entry:</u> Mar/26/2021 | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Consent Was:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--|---------------|
| Mar-26-2021 10:21:14 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: OBTAINED Date Written Consent Obtained Mar/26/2021 | Initial Entry |

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History
Unscheduled

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

Site No: 1039 **Site Name:** (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[Back to Form](#)

1. Data Origin

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|----------------------------|---------------|
| Mar-26-2021 10:21:34 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|-----------------------------|---------------|
| Mar-26-2021 10:21:34 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------------|--------------------|---|
| Mar-26-2021 13:45:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Mar-26-2021 10:21:34 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History
Unscheduled

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

Site No: 1039 Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|---|-------------------------|---------------------|---|------------------------------------|
| | | | | review and correct as appropriate. |
| Mar-26-2021 10:21:34 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Mar/26/2021 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--|---------------|
| Mar-26-2021 13:45:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Sample ID: BLBDNB | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|------------------------------|---------------|
| Mar-26-2021 13:45:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: BLBDNB | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--|---------------|
| Mar-26-2021 13:45:35 (UTC-06:00) Central | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Sample ID: BRGCKT | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History
Unscheduled

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

Site No: 1039 **Site Name:** (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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

5.b Sample ID

| Date | Location | User | Value | Reason |
|--|-------------------------|------------------------|------------------------------|---------------|
| Mar-26-2021 13:45:35 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: BRGCKT | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|--|-------------------------|------------------------|--|---------------|
| Mar-26-2021 13:45:46 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Sample ID: BRGCKV | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|--|-------------------------|------------------------|------------------------------|---------------|
| Mar-26-2021 13:45:46 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: BRGCKV | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING - NASAL
Unscheduled SWAB - eCRF Audit Trail History

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

Site No: 1039 **Site Name:** (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|----------------------------|---------------|
| Mar-26-2021 10:21:56 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|----------------------------------|---------------|
| Mar-26-2021 10:21:56 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------------|--------------------|---|
| Mar-26-2021 13:44:58 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Mar-26-2021 10:21:56 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING - NASAL
Unscheduled SWAB - eCRF Audit Trail History

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

Site No: 1039 **Site Name:** (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

| | | | | |
|--|-------------------------|---------------------|---|------------------------------------|
| | | | | review and correct as appropriate. |
| Mar-26-2021 10:21:56 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Mar/26/2021 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--|---------------|
| Mar-26-2021 13:44:58 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Sample ID: BRMFT9 | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|------------------------------|---------------|
| Mar-26-2021 13:44:58 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: BRMFT9 | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

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

Form Version: 10-Dec-2020 02:29 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1039 **Site Name:** (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|----------------------------------|---------------|
| Feb-05-2021 10:28:09 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Feb/5/2021 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|-----------------------------------|---------------|
| Feb-05-2021 10:28:09 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: VACCINATION | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|---------------------------------|---------------|
| Feb-05-2021 10:28:09 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 -
Unscheduled Visit on Apr/09/2021

Form Version: 14-Jan-2021 02:22

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|----------------------------------|---------------|
| Apr-12-2021 09:01:47 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Apr/9/2021 | Initial Entry |

3. COVID-19 Surveillance Visit:

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|-----------------------------------|---------------|
| Apr-12-2021 09:01:47 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: SSWAB_WEEK2 | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 -
Unscheduled Visit on Apr/09/2021

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

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|----------------------------|---------------|
| Apr-12-2021 09:02:01 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|---------------------------------------|---------------|
| Apr-12-2021 09:02:01 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NASAL_SWAB_SELF | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------------|--------------------|---|
| Apr-12-2021 09:02:33 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Apr-12-2021 09:02:01 (UTC-06:00) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 1 -
Unscheduled Visit on Apr/09/2021

Form Version: 10-Oct-2020 15:57

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|--|-------------------------|---------------------|--|--|
| Central Time (US & Canada) | | | | no barcodes are entered. Please review and correct as appropriate. |
| Apr-12-2021 09:02:01 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Apr/9/2021 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|---|---------------|
| Apr-12-2021 09:02:33 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Sample ID: AA00171 | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|-------------------------------|---------------|
| Apr-12-2021 09:02:33 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: AA00171 | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 2 -
Unscheduled Visit on Apr/22/2021

Form Version: 14-Jan-2021 02:22

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|-----------------------------------|------------------------|
| Apr-23-2021 08:16:35 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Apr/22/2021 | Transcription Error |
| Apr-23-2021 08:13:25 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Apr/23/2021 | Initial Entry |

3. COVID-19 Surveillance Visit:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|-----------------------------------|---------------|
| Apr-23-2021 08:13:25 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: SSWAB_WEEK4 | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 2 -
Unscheduled Visit on Apr/22/2021

Form Version: 10-Oct-2020 15:57

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|----------------------------|---------------|
| Apr-23-2021 08:15:50 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|---------------------------------------|---------------|
| Apr-23-2021 08:15:50 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NASAL_SWAB_SELF | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|-------------------|-----------------------------|
| May-04-2021 09:50:32 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Query 3: Closed | Response satisfies query |
| Apr-27-2021 11:44:55 (UTC-06:00) Central Time (US & | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Query 3: Answered | Task is complete |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 2 -
Unscheduled Visit on Apr/22/2021

Form Version: 10-Oct-2020 15:57

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|---|-------------------------|--------------------------------|--------------------|---|
| Canada) | | | | |
| Apr-27-2021 11:08:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) [REDACTED] | Query 3: Opened | Please upload source documents into Florence. |
| Apr-23-2021 08:16:35 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 2: Closed | Close Auto Query |
| Apr-23-2021 08:16:15 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Apr-23-2021 08:15:50 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 2: Opened | Date of Collection is different from Date of Visit. Please review and update as appropriate, else clarify. |
| Apr-23-2021 08:15:50 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 2 -
Unscheduled Visit on Apr/22/2021

Form Version: 10-Oct-2020 15:57

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|---|-------------------------|------------------|---|-------------------------|
| | | | | correct as appropriate. |
| Apr-23-2021 08:15:50 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Apr/22/2021 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|---|---------------|
| Apr-23-2021 08:16:15 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Sample ID: AA01236 | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|-------------------------------|---------------|
| Apr-23-2021 08:16:15 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: AA01236 | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 3 -
Unscheduled Visit on May/06/2021

Form Version: 14-Jan-2021 02:22

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: DATE OF VISIT - ASYMPTOMATIC
SURVEILLANCE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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1. Date of Visit

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|----------------------------------|------------------------|
| May-07-2021 10:55:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: May/6/2021 | Changed Information |
| May-07-2021 10:54:42 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: May/7/2021 | Initial Entry |

3. COVID-19 Surveillance Visit:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|-----------------------------------|---------------|
| May-07-2021 10:54:42 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: SSWAB_WEEK6 | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 3 -
Unscheduled Visit on May/06/2021

Form Version: 10-Oct-2020 15:57

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|----------------------------|---------------|
| May-07-2021 10:54:59 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|---------------------------------------|---------------|
| May-07-2021 10:54:59 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NASAL_SWAB_SELF | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|-------------------|------------------------------|
| May-12-2021 17:54:49 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Query 3: Closed | Response satisfies query |
| May-10-2021 12:34:20 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Query 3: Answered | Original value is correct |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 3 -
Unscheduled Visit on May/06/2021

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

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|--|-------------------------|---------------------------|---------------------------|---|
| May-10-2021 12:21:53 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Query 3: Opened | Please upload source documents in Florence. |
| May-07-2021 10:55:34 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| May-07-2021 10:55:19 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 2: Closed | Close Auto Query |
| May-07-2021 10:54:59 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 2: Opened | Date of Collection is different from Date of Visit. Please review and update as appropriate, else clarify. |
| May-07-2021 10:54:59 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| May-07-2021 10:54:59 | ACV0PF EINFP60 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V202_SURVEIL_SWAB 3 -
Unscheduled Visit on May/06/2021

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

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|---|----|------------------|---------------------------------------|--|
| (UTC-06:00) Central Time (US & Canada) | 00 | (b) (4), (b) (6) | Date of Collection: May/6/2021 | |
|---|----|------------------|---------------------------------------|--|

5.a

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|---|---------------|
| May-07-2021 10:55:34 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Sample ID: AA00189 | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|-------------------------------|---------------|
| May-07-2021 10:55:34 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: AA00189 | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

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

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

Site No: 1039 **Site Name:** (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|-----------------------------------|---------------|
| May-13-2021 09:29:24 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: May/12/2021 | Initial Entry |

Header Text: c4591001

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

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

Site No: 1039 **Site Name:** (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|---|---------------|
| May-13-2021 09:29:45 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: 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 | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------------|--------------|--------|
| Jun-04-2021 09:57:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Form Created | |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------------|--------------|--------|
| Jun-04-2021 09:58:51 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Form Created | |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------------|--------------|--------|
| Jun-04-2021 10:00:24 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Form Created | |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------------|--------------|--------|
| Jul-12-2021 15:34:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Form Created | |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------------|--------------|--------|
| Jul-12-2021 15:35:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Form Created | |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------------|--------------|--------|
| Jul-12-2021 15:36:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Form Created | |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|--------|
| Jul-13-2021 10:48:54 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Category:

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|-------------------------------------|---------------|
| Jun-04-2021 09:57:25 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|-------------------------|---------------|
| Jun-04-2021 09:57:25 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: 1 | Initial Entry |

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|-------------------------------|---------------|
| Jun-04-2021 09:57:25 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: fatigue | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|---|---------------|
| Jun-04-2021 09:57:25 (UTC-06:00) Central | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: May/14/2021 18:00 | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Time (US & Canada)

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|---|---------------|
| Jun-04-2021 09:57:25 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO End Date Time: May/15/2021 18:00 | Initial Entry |

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|-------------------------|---------------|
| Jun-04-2021 09:57:25 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (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 |
|-------------------------|-------------------|------------------|--------------------------|---------------|
| Jun-04-2021 09:57:25 | ACV0PF EINFP60 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

00

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

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 |
|--|-------------------------|---------------------|--------------------------|---------------|
| Jun-04-2021 09:57:25 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

9. Is this event related to study treatment:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|-------------------------------|---------------|
| Jun-04-2021 09:57:25 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | <u>Data Entry:</u> RELATED | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------------------|---------------|
| Jun-04-2021 09:57:25 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | <u>Data Entry:</u> NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

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

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|--|-------------------------|---------------------|--------------------------|---------------|
| Jun-04-2021 09:57:25 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |
|--|-------------------------|---------------------|--------------------------|---------------|

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------|---------------|
| Jun-04-2021 09:57:56 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--|---------------|
| Jun-04-2021 09:57:25 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: RECOVERED/RESOLVED | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------|---------------|
| Jun-04-2021 09:57:25 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Category:

| Date | Location | User | Value | Reason |
|---|-------------------------|-------------------------|-------------------------------------|---------------|
| Jun-04-2021 09:58:51 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|---|-------------------------|-------------------------|-------------------------|---------------|
| Jun-04-2021 09:58:51 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: 2 | Initial Entry |

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|------------------------------|---------------|
| Jun-04-2021 09:58:51 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: nausea | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|-------------------------|-------------------|------------------|---|---------------|
| Jun-04-2021 09:58:51 | ACV0PF EINFP60 | (b) (4), (b) (6) | Data Entry: May/14/2021 18:00 | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

00

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

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|---|---------------|
| Jun-04-2021 09:58:51 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO End Date Time: May/15/2021 18:00 | Initial Entry |

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|-------------------------|---------------|
| Jun-04-2021 09:58:51 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (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 |
|-------------|----------|------------------|--------------------|---------------|
| Jun-04-2021 | ACV0PF | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|--|---------------|---------------------|----|--|
| 09:58:51 (UTC-06:00) Central Time (US & Canada) | EINFP60 00 | (b) (4), (b) (6) | 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 |
|---|-------------------------|---------------------|--------------------------|---------------|
| Jun-04-2021 09:58:51 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

9. Is this event related to study treatment:

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|-------------------------------|---------------|
| Jun-04-2021 09:58:51 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: RELATED | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--------------------------------------|---------------|
| Jun-04-2021 09:58:51 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| Date | Location | User | Value | Reason |
|---|-------------------------|-----------------------------------|--------------------------|---------------|
| Jun-04-2021 09:58:51 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) [REDACTED] | Data Entry: NO | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|---|-------------------------|-----------------------------------|--------------------------|---------------|
| Jun-04-2021 09:58:51 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) [REDACTED] | Data Entry: NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-------------------------|-----------------------------------|--|---------------|
| Jun-04-2021 09:58:51 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) [REDACTED] | Data Entry: RECOVERED/RESOLVED | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-------------------------|-----------------------------------|--------------------------|---------------|
| Jun-04-2021 09:58:51 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) [REDACTED] | Data Entry: NO | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Category:

| Date | Location | User | Value | Reason |
|---|-------------------------|-------------------------|-------------------------------------|---------------|
| Jun-04-2021 10:00:24 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|---|-------------------------|-------------------------|-------------------------|---------------|
| Jun-04-2021 10:00:24 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: 3 | Initial Entry |

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|---|---------------|
| Jun-04-2021 10:00:24 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: injection site pain | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|-------------------------|-------------------|------------------|---|---------------|
| Jun-04-2021 10:00:24 | ACV0PF EINFP60 | (b) (4), (b) (6) | Data Entry: May/15/2021 08:00 | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

00

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

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|---|---------------|
| Jun-04-2021 10:00:24 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO End Date Time: May/15/2021 UNK:UNK | Initial Entry |

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|-------------------------|---------------|
| Jun-04-2021 10:00:24 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (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 |
|-------------|----------|------------------|--------------------|---------------|
| Jun-04-2021 | ACV0PF | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|--|---------------|---------------------|----|--|
| 10:00:24 (UTC-06:00) Central Time (US & Canada) | EINFP60 00 | (b) (4), (b) (6) | 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 |
|---|-------------------------|---------------------|--------------------------|---------------|
| Jun-04-2021 10:00:24 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

9. Is this event related to study treatment:

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|-------------------------------|---------------|
| Jun-04-2021 10:00:24 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: RELATED | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--------------------------------------|---------------|
| Jun-04-2021 10:00:24 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--------------------------|---------------|
| Jun-04-2021 10:00:24 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--------------------------|---------------|
| Jun-04-2021 10:00:24 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--|---------------|
| Jun-04-2021 10:00:24 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: RECOVERED/RESOLVED | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--------------------------|---------------|
| Jun-04-2021 10:00:24 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Category:

| Date | Location | User | Value | Reason |
|---|-------------------------|-------------------------|-------------------------------------|---------------|
| Jul-12-2021 15:34:32 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|---|-------------------------|-------------------------|-------------------------|---------------|
| Jul-12-2021 15:34:32 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: 4 | Initial Entry |

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|-----------------------------|---------------|
| Jul-12-2021 15:34:32 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: fever | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|-------------------------|-------------------|---------------------|--|---------------|
| Jul-12-2021 15:34:32 | ACV0PF EINFP60 | (b) (4), (b) (6) | Data Entry: Jun/4/2021 14:00 | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|--|----|------------------|--|--|
| (UTC-06:00) Central Time (US & Canada) | 00 | (b) (4), (b) (6) | | |
|--|----|------------------|--|--|

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--|---------------|
| Jul-12-2021 15:34:32 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO End Date Time: Jun/5/2021 UNK:UNK | Initial Entry |

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|-------------------------|---------------|
| Jul-12-2021 15:34:32 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (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 |
|-------------|----------|------------------|--------------------|---------------|
| Jul-12-2021 | ACV0PF | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|---|---------------|---------------------|----|--|
| 15:34:32 (UTC-06:00) Central Time (US & Canada) | EINFP60 00 | (b) (4), (b) (6) | 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 |
|--|-------------------------|---------------------|--------------------------|---------------|
| Jul-12-2021 15:34:32 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

9. Is this event related to study treatment:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|-------------------------------|---------------|
| Jul-12-2021 15:34:32 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: RELATED | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------------------|---------------|
| Jul-12-2021 15:34:32 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--------------------------|---------------|
| Jul-12-2021 15:34:32 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--------------------------|---------------|
| Jul-12-2021 15:34:32 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--|---------------|
| Jul-12-2021 15:34:32 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: RECOVERED/RESOLVED | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--------------------------|---------------|
| Jul-12-2021 15:34:32 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Category:

| Date | Location | User | Value | Reason |
|---|-------------------------|-------------------------|-------------------------------------|---------------|
| Jul-12-2021 15:35:27 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|---|-------------------------|-------------------------|-------------------------|---------------|
| Jul-12-2021 15:35:27 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: 5 | Initial Entry |

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|------------------------------|---------------|
| Jul-12-2021 15:35:27 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: nausea | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|-------------------------|-------------------|------------------|--|---------------|
| Jul-12-2021 15:35:27 | ACV0PF EINFP60 | (b) (4), (b) (6) | Data Entry: Jun/4/2021 14:00 | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

00

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

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--|---------------|
| Jul-12-2021 15:35:27 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO End Date Time: Jun/5/2021 UNK:UNK | Initial Entry |

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|-------------------------|---------------|
| Jul-12-2021 15:35:27 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (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 |
|-------------|----------|------------------|--------------------|---------------|
| Jul-12-2021 | ACV0PF | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

15:35:27
(UTC-06:00) Central
Time (US & Canada)

EINFP60
00

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

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 |
|--|-------------------------|---------------------|--------------------------|---------------|
| Jul-12-2021 15:35:27 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

9. Is this event related to study treatment:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|-------------------------------|---------------|
| Jul-12-2021 15:35:27 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: RELATED | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------------------|---------------|
| Jul-12-2021 15:35:27 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--------------------------|---------------|
| Jul-12-2021 15:35:27 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--------------------------|---------------|
| Jul-12-2021 15:35:27 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--|---------------|
| Jul-12-2021 15:35:27 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: RECOVERED/RESOLVED | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--------------------------|---------------|
| Jul-12-2021 15:35:27 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Category:

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|-------------------------------------|---------------|
| Jul-12-2021 15:36:16 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|-------------------------|---------------|
| Jul-12-2021 15:36:16 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: 6 | Initial Entry |

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

| Date | Location | User | Value | Reason |
|--|---|---------------------------|-------------------|------------------------------|
| Jul-13-2021 13:03:10 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00.InFor mAdapte r.Discrep ancy | PFETMS Oracle (b) (4) | Query 1: Closed | Discrepancy has been closed. |
| Jul-13-2021 10:49:24 (UTC-06:00) Central Time (US & | ACV0PF EINFP60 00 | auto query (autoquery) | Query 1: Answered | Changed Information |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|--|---|--------------------------|---|--|
| Canada) | | | | |
| Jul-13-2021 10:49:24 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: muscle aches | Changed Information |
| Jul-12-2021 17:07:48 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00.InFor mAdapte r.Discrep ancy | PFETMS Oracle (b) (4) | Query 1: Opened | Multiple concepts in the term MUSCLE AND JOINT PAIN. Please split the term into MUSCLE PAIN and JOINT PAIN and submit separately. Thank you. |
| Jul-12-2021 15:36:16 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: muscle and joint pain | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--|---------------|
| Jul-12-2021 15:36:16 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Jun/4/2021 14:00 | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--|---------------|
| Jul-12-2021 15:36:16 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO End Date Time: Jun/5/2021 UNK:UNK | Initial Entry |

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|-------------------------|---------------|
| Jul-12-2021 15:36:16 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (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 |
|---|-------------------------|---------------------|--------------------------|---------------|
| Jul-12-2021 15:36:16 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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 |
|--|-------------------------|---------------------|--------------------------|---------------|
| Jul-12-2021 15:36:16 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

9. Is this event related to study treatment:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|-------------------------------|---------------|
| Jul-12-2021 15:36:16 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: RELATED | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------------------|---------------|
| Jul-12-2021 15:36:16 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------|---------------|
| Jul-12-2021 15:36:16 (UTC-06:00) Central | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Time (US & Canada)

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------|---------------|
| Jul-12-2021 15:36:16 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--|---------------|
| Jul-12-2021 15:36:16 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: RECOVERED/RESOLVED | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------|---------------|
| Jul-12-2021 15:36:16 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Category:

| Date | Location | User | Value | Reason |
|---|-------------------------|-------------------------|-------------------------------------|---------------|
| Jul-13-2021 10:48:54 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|---|-------------------------|-------------------------|-------------------------|---------------|
| Jul-13-2021 10:48:54 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: 7 | Initial Entry |

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------------|-------------------|-----------------------------|
| Jul-15-2021 14:51:54 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Jul-15-2021 11:33:11 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 1: Answered | Changed Information |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|--|-------------------------|---------------------|--|--|
| Jul-15-2021 11:33:11 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Generalized Arthralgia | Changed Information |
| Jul-14-2021 10:40:40 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Query 1: Opened | clinical-pls update CRF to indicate specific joints involved or if generalized joint pain. Thanks |
| Jul-13-2021 10:48:54 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Arthralgia | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--|---------------|
| Jul-13-2021 10:48:54 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Jun/4/2021 14:00 | Initial Entry |

5. Is the adverse event still ongoing?

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

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|--|-------------------------|---------------------|--|---------------|
| Jul-13-2021 10:48:54 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO End Date Time: Jun/5/2021 UNK:UNK | Initial Entry |
|--|-------------------------|---------------------|--|---------------|

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|-------------------------|---------------|
| Jul-13-2021 10:48:54 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (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 |
|--|-------------------------|---------------------|--------------------------|---------------|
| Jul-13-2021 10:48:54 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------|---------------|
| Jul-13-2021 10:48:54 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

9. Is this event related to study treatment:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|-------------------------------|---------------|
| Jul-13-2021 10:48:54 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: RELATED | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------------------|---------------|
| Jul-13-2021 10:48:54 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

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

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|--|-------------------------|---------------------|--------------------------|---------------|
| Jul-13-2021 10:48:54 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |
|--|-------------------------|---------------------|--------------------------|---------------|

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------|---------------|
| Jul-13-2021 10:48:54 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--|---------------|
| Jul-13-2021 10:48:54 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: RECOVERED/RESOLVE D | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------|---------------|
| Jul-13-2021 10:48:54 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|---------|--|--|--|--|
| Canada) | | | | |
|---------|--|--|--|--|

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:27

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date Treatment Unblinded :

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|-----------------------------------|---------------|
| May-13-2021 09:29:05 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: May/12/2021 | Initial Entry |

2. Primary Reason for Unblinding:

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|---|---------------|
| May-13-2021 09:29:05 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: ASSESS ELIGIBILITY F OR ADDITIONAL VAC CINATION | Initial Entry |

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Visit

| Date | Location | User | Value | Reason |
|--|-------------------------|-----------------------------------|-----------------------------------|---------------|
| May-14-2021 10:02:49 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) [Redacted] | Data Entry: May/14/2021 | 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: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Consent Was:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--|---------------|
| May-14-2021 10:03:57 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: OBTAINED Date Written Consent Obtained May/14/2021 | Initial Entry |

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: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|-----------------------------------|---------------|
| May-14-2021 10:05:24 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: May/14/2021 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-------------------------|-------------------------|--|---------------|
| May-14-2021 10:05:24 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: REPEAT SCREENING 1 | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|---------------------------------|---------------|
| May-14-2021 10:05:24 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 30-Apr-2021 01:41

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Lab Panel:

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|----------------------------------|---------------|
| May-14-2021 10:06:03 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: URINALYSIS | Initial Entry |

2. Lab Sub-Panel:

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|---------------------------------|---------------|
| May-14-2021 10:06:03 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: PREGNANCY | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|-----------------------------------|---------------|
| May-14-2021 10:06:03 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: May/14/2021 | Initial Entry |

4. Laboratory Name and Address (Derived)

| Date | Location | User | Value | Reason |
|-------------|----------|-----------|--------------------|---------------|
| May-14-2021 | ACV0PF | auto calc | Data Entry: | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 30-Apr-2021 01:41

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|---|---------------|------------|------------|--|
| 10:06:03 (UTC-06:00) Central Time (US & Canada) | EINFP60 00 | (autocalc) | STUDY SITE | |
|---|---------------|------------|------------|--|

5. Specimen Type:

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|-----------------------------|---------------|
| May-14-2021 10:06:03 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: URINE | Initial Entry |

6.a

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|--|---------------|
| May-14-2021 10:06:03 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: Sponsor-Def 113 ined Identifi er: Test:: Choriogonadot ropin Beta_PX 113 Result:: Not Done:: NOT DONE | Initial Entry |

6.a Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|---------------------------|---------------|
| May-14-2021 10:06:03 (UTC-06:00) Central | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: 113 | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 30-Apr-2021 01:41

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Time (US & Canada)

6.a Test:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|---|---------------|
| May-14-2021 10:06:03 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Choriogonadotropin Beta_P X113 | Initial Entry |

6.a Not Done:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------------|---------------|
| May-14-2021 10:06:03 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NOT DONE | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (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: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Data Origin

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|----------------------------|---------------|
| May-14-2021 10:06:20 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|-----------------------------|---------------|
| May-14-2021 10:06:20 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------------|--------------------|---|
| May-14-2021 16:57:12 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| May-14-2021 10:06:20 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (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: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|---|-------------------------|---------------------|---|------------------------------------|
| | | | | review and correct as appropriate. |
| May-14-2021 10:06:20 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: May/14/2021 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-------------------------|------------------|--|---------------|
| May-14-2021 16:57:12 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Sample ID: BRDP7D | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-------------------------|------------------|------------------------------|---------------|
| May-14-2021 16:57:12 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: BRDP7D | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|--|-------------------------|------------------|--|---------------|
| May-14-2021 16:58:05 (UTC-06:00) Central | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Sample ID: BRDP7F | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (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: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-------------------------|------------------|------------------------------|---------------|
| May-14-2021 16:58:05 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: BRDP7F | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-------------------------|------------------|---|---------------|
| May-14-2021 17:07:11 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Sample ID: BLBDDDB | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|---|-------------------------|------------------|-------------------------------|---------------|
| May-14-2021 17:07:11 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: BLBDDDB | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (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: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|----------------------------|---------------|
| May-14-2021 10:06:32 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|----------------------------------|---------------|
| May-14-2021 10:06:32 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------------|--------------------|---|
| May-14-2021 16:46:03 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| May-14-2021 10:06:32 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (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: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|---|-------------------------|---------------------|---|------------------------------------|
| | | | | review and correct as appropriate. |
| May-14-2021 10:06:32 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: May/14/2021 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-------------------------|------------------|--|---------------|
| May-14-2021 16:46:03 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Sample ID: BRMFWG | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-------------------------|------------------|------------------------------|---------------|
| May-14-2021 16:46:03 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: BRMFWG | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------|---------------|
| May-14-2021 10:07:32 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2. Treatment Name

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|--------------------------------|---------------|
| May-14-2021 10:07:32 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: BNT162b2 | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|---------------------------------|---------------|
| May-14-2021 10:07:32 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: INJECTION | Initial Entry |

4. Dose Date Time:

| Date | Location | User | Value | Reason |
|-------------------------|-------------------|------------------|---|---------------|
| May-14-2021 10:07:32 | ACV0PF EINFP60 | (b) (4), (b) (6) | Data Entry: May/14/2021 08:35 | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|--|----|------------------|--|--|
| (UTC-06:00) Central Time (US & Canada) | 00 | (b) (4), (b) (6) | | |
|--|----|------------------|--|--|

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|---|-------------------------|-------------------------|--------------------------------------|---------------|
| May-14-2021 10:07:32 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|----------------------------|---------------|
| May-14-2021 10:07:32 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: LEFT | Initial Entry |

7. Route:

| Date | Location | User | Value | Reason |
|---|-------------------------|-------------------------|-------------------------------------|---------------|
| May-14-2021 10:07:32 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

8. Actual Dose:

| Date | Location | User | Value | Reason |
|-------------------------|-------------------|-------------------------|----------------------------|---------------|
| May-14-2021 10:07:32 | ACV0PF EINFP60 | auto calc (autocalc) | Data Entry: 30.0 | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

9. Unit:

| Date | Location | User | Value | Reason |
|---|-------------------------|-------------------------|--------------------------|---------------|
| May-14-2021 10:07:32 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: ug | Initial Entry |

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|---|-------------------------|-------------------------|----------------------------------|---------------|
| May-14-2021 10:07:32 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: 30 MINUTES | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|---------------------------|---------------|
| May-14-2021 10:07:32 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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1. Date of Visit

| Date | Location | User | Value | Reason |
|--|-------------------------|-----------------------------------|----------------------------------|---------------|
| Jun-04-2021 09:54:13 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) [Redacted] | Data Entry: Jun/4/2021 | Initial Entry |

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 30-Apr-2021 01:41

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Lab Panel:

| Date | Location | User | Value | Reason |
|---|-------------------------|-------------------------|----------------------------------|---------------|
| Jun-04-2021 09:54:25 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: URINALYSIS | Initial Entry |

2. Lab Sub-Panel:

| Date | Location | User | Value | Reason |
|---|-------------------------|-------------------------|---------------------------------|---------------|
| Jun-04-2021 09:54:25 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: PREGNANCY | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|----------------------------------|---------------|
| Jun-04-2021 09:54:25 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Jun/4/2021 | Initial Entry |

4. Laboratory Name and Address (Derived)

| Date | Location | User | Value | Reason |
|---|-------------------------|-------------------------|----------------------------------|---------------|
| Jun-04-2021 09:54:25 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: STUDY SITE | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 30-Apr-2021 01:41

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

5. Specimen Type:

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|-----------------------------|---------------|
| Jun-04-2021 09:54:25 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: URINE | Initial Entry |

6.a

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|--|---------------|
| Jun-04-2021 09:54:25 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: Sponsor-Defined Identifier: Test:: Choriogonadotropin Beta_PX 113 Result:: Not Done:: NOT DONE | Initial Entry |

6.a Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|---------------------------|---------------|
| Jun-04-2021 09:54:25 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: 113 | Initial Entry |

6.a Test:

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

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 30-Apr-2021 01:41

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|--|-------------------------|---------------------|---|---------------|
| Jun-04-2021 09:54:25 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Choriogonadotropin Beta_P X113 | Initial Entry |
|--|-------------------------|---------------------|---|---------------|

6.a Not Done:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------------|---------------|
| Jun-04-2021 09:54:25 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NOT DONE | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-------------------------|-------------------------|----------------------------|---------------|
| Jun-04-2021 09:54:38 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-------------------------|-------------------------|----------------------------------|---------------|
| Jun-04-2021 09:54:38 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------------|--------------------|---|
| Jun-04-2021 14:38:32 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Jun-04-2021 09:54:38 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|---|-------------------------|---------------------|--|---------------|
| | | | | appropriate. |
| Jun-04-2021 09:54:38 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Jun/4/2021 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-------------------------|------------------|--|---------------|
| Jun-04-2021 14:38:32 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Sample ID: BRMFXW | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-------------------------|------------------|------------------------------|---------------|
| Jun-04-2021 14:38:32 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: BRMFXW | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--------------------------|---------------|
| Jun-04-2021 09:55:28 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2. Treatment Name

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|--------------------------------|---------------|
| Jun-04-2021 09:55:28 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: BNT162b2 | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|---------------------------------|---------------|
| Jun-04-2021 09:55:28 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: INJECTION | Initial Entry |

4. Dose Date Time:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|--|---------------|
| Jun-04-2021 09:55:28 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Jun/4/2021 08:16 | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|--------------------------------------|---------------|
| Jun-04-2021 09:55:28 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|----------------------------|---------------|
| Jun-04-2021 09:55:28 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: LEFT | Initial Entry |

7. Route:

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|-------------------------------------|---------------|
| Jun-04-2021 09:55:28 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

8. Actual Dose:

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|----------------------------|---------------|
| Jun-04-2021 09:55:28 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: 30.0 | Initial Entry |

9. Unit:

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

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|---|-------------------------|-------------------------|--------------------------|---------------|
| Jun-04-2021 09:55:28 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: ug | Initial Entry |
|---|-------------------------|-------------------------|--------------------------|---------------|

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|---|-------------------------|-------------------------|----------------------------------|---------------|
| Jun-04-2021 09:55:28 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: 30 MINUTES | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|---------------------------|---------------|
| Jun-04-2021 09:55:28 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Visit

| Date | Location | User | Value | Reason |
|--|---|-------------------------|-------------------|--|
| Jul-15-2021 00:10:18 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Query 1: Closed | As per site confirmation - updated PD tracker |
| Jul-14-2021 07:22:01 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Query 1: Answered | Date is correct. PD has been submitted. |
| Jul-14-2021 01:46:58 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00.InFor mAdapte r.Discrep ancy | PFE SDQ PROD (b) (4) | Query 1: Opened | PDQ: Date of visit V103_MONTH1 is out of window for 3 days from V102_VAX4 DOV or Vaccination date. Please verify and update. Else, confirm in query response appropriately. (b) (4) |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|---|-------------------------|--------------------------------|-----------------------------------|---------------|
| Jul-12-2021 15:13:18 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) [REDACTED] | Data Entry: Jul/12/2021 | Initial Entry |
|---|-------------------------|--------------------------------|-----------------------------------|---------------|

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form: CONTACT OUTCOME - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Contact Type:

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|---------------------------------------|---------------|
| Jul-12-2021 15:13:32 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: TELEPHONE VISIT | Initial Entry |

2. Was contact made?

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|--|---------------|
| Jul-12-2021 15:13:32 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: YES Date of Contact: Jul/12/2021 | Initial Entry |

Header Text: c4591001

Visit:
FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit
Trail History

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Date of Completion/Discontinuation/Death :

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|-----------------------------------|---------------|
| Jul-12-2021 15:13:44 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: Jul/12/2021 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-------------------------|-------------------------|--|---------------|
| Jul-12-2021 15:13:44 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: OPEN LABEL TREATMENT | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|--|-------------------------|---------------------|---------------------------------|---------------|
| Jul-12-2021 15:13:44 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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1. Subject Status

| Date | Location | User | Value | Reason |
|--|-------------------------|-------------------------|---|---------------|
| Feb-05-2021 10:28:09 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: FOLLOW-UP | Initial Entry |
| Dec-18-2020 13:45:16 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: ENROLLED/RANDOMIZED | Initial Entry |
| Dec-18-2020 13:38:40 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: SCREENED | Initial Entry |

2. Subject Status Date

| Date | Location | User | Value | Reason |
|---|-------------------------|---------------------|-------------------|---|
| Jul-27-2021 11:00:06 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Jul-26-2021 22:33:02 (UTC-06:00) Central Time (US & | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Query 1: Answered | illness visit not required. entry was made in error. |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1039

Site Name: (1039) ARC Clinical Research at Wilson Parke

Subject No: 10391285

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

| | | | | |
|---|-------------------------|-------------------------|-----------------------------------|---|
| Canada) | | | | documented in unplanned crf |
| Jul-26-2021 21:55:05 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | (b) (4), (b) (6) | Query 1: Opened | 10391285 reported a potential COVID symptom via eDiary on 23-Jul-2021. Please confirm if a COVID Illness Visit is required or fi this a data entry error. |
| Feb-05-2021 10:28:09 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: Feb/5/2021 | Initial Entry |
| Dec-18-2020 13:45:16 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: Dec/18/2020 | Initial Entry |
| Dec-18-2020 13:38:40 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | auto calc (autocalc) | Data Entry: Dec/18/2020 | Initial Entry |

090177e19891a043\Final\Final On: 11-Nov-2021 01:21 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1039

Subject No: 10391285

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1039) ARC Clinical Research at Wilson
Parke

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

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1. Casebook Signature

| Date | Location | User | Value | Reason |
|--|-------------------------|------------------------------|--|---------------|
| Mar-10-2021 14:46:41 (UTC-06:00) Central Time (US & Canada) | ACV0PF EINFP60 00 | Gretchen Crook (b) (4) | Data Entry: Click Here to Enable | Initial Entry |