

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 10-Dec-2020 02:31

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: COHORT_SELECTION

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[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 Version: 22-Apr-2020 21:02

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/12/2021
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 10-Dec-2020 02:26

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: DEMOGRAPHY

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10391337]
2.	Birth Date:	(b) (6) 2005
3.	Sex:	MALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1039

Subject No: 10391337

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): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/12/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Jan/12/2021
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: 10391337

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[penicillin allergy]
	Start Date:	UNK/UNK/2007
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[acne]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[eczema, bilateral arms]
	Start Date:	UNK/UNK/2012
	Ongoing:	NO End Date: UNK/UNK/2012
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[tonsillectomy]
	Start Date:	UNK/UNK/2011
	Ongoing:	NO End Date: UNK/UNK/2011

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[recurrent diarrhea]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: HIV STATUS

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[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:** 10391337**Generated By:** (b) (4)**Form:** VITAL SIGNS - BASELINE**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1039) ARC Clinical Research at Wilson Parke**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[eCRF Audit Trail History](#)**Vital Signs**

1.	Date:	Jan/12/2021
2.	Weight:	[84.7]
3.	Unit:	kg
4.	Height:	[182.4]
5.	Unit:	cm
6.	Body Mass Index:	[25.5]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.8]
	Unit:	C
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Jan/12/2021
2.	Randomization Number:	[26822]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/12/2021
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	[BRJBTF]
5.b	Sample ID	[BRJB TG]
5.c	Sample ID	[BS6HBS]

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/12/2021
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	[BRJBCH]
-----	-----------	----------

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 10-Dec-2020 02:26**Site No:** 1039**Subject No:** 10391337**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):** 06-Apr-2021 15:36**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/12/2021 12:09
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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1039

Subject No: 10391337

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): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/3/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[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
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

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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
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

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 14-Jan-2021 02:22

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Feb/3/2021
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Vital Signs Details

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

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1039**Subject No:** 10391337**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1039) ARC Clinical Research at Wilson Parke**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36**eCRF Audit Trail History****Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/3/2021
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	[BRMFPPK]
-----	-----------	-----------

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 10-Dec-2020 02:26**Site No:** 1039**Subject No:** 10391337**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):** 06-Apr-2021 15:36**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:	Feb/3/2021 07:51
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

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1039

Subject No: 10391337

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): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/9/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[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
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

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (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, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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
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

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Mar/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	[BRGCHR]
5.b	Sample ID	[BRGCHS]
5.c	Sample ID	[BLBDLF]

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1039

Subject No: 10391337

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): 06-Apr-2021 15:36

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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	[]
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090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1039

Subject No: 10391337

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): 06-Apr-2021 15:36

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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	[]
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090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001**Visit:** V6_MONTH24_L**Form Version:** 22-Apr-2020 21:02**Site No:** 1039**Subject No:** 10391337**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):** 06-Apr-2021 15:36**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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	[]
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090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET
on Jan/22/2021

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: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/22/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
on Jan/22/2021

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Signs and Symptoms

1.	Date of Assessment:	Jan/22/2021
2.	Date of First Symptom Started:	Jan/22/2021
3.	Symptoms Ongoing?	NO
	Date of Last Symptom Resolved:	Jan/24/2021

Symptoms

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

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
on Jan/22/2021

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

4.i	Symptoms:	VOMITING
	Was symptom present?	NO

Symptoms - Other

5.a	Symptoms - Other Text:	[nausea]
-----	------------------------	----------

5.b	Symptoms - Other Text:	[erythema, left pectoral]
-----	------------------------	---------------------------

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Jan/23/2021	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN
on Jan/22/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Not Complete

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Microbiology Specimen

1.	Actual Date of Collection:	Jan/23/2021	Comments
2.	Specimen Type:	SWABBED MATERIAL	Comments
3.	Specimen Collection Location:	NASOPHARYNX	Comments
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	Comments
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST	Comments
6.	Trade Name:	OTHER	Comments
7.	Test Result:	NEGATIVE	Comments
8.	Comments/Findings/Details:	[]	Comments
9.	Trade Name Other, Specify:	[Curative-Korva SARS-Cov-2 Assay]	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Jan/22/2021

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: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Jan/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	[RR10921]
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090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
on Jan/22/2021**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:** 10391337**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Patient will collect self swab.]

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION
on Jan/22/2021**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete, Frozen, Verified**Site No:** 1039**Site Name:** (1039) ARC Clinical Research at Wilson Parke**Subject No:** 10391337**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[eCRF Audit Trail History](#)**Health Care Utilization**

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

Health Care Utilization Other

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

Health Care Utilization

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT
on Jan/22/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Respiratory Treatment

1.	What is the treatment Identifier?	Not Done _____ []	Comments
2.	Concomitant Non-drug Treatment Pre-specified:	Not Done _____	Comments
3.	Treatment:	Not Done _____	Comments
4.	Treatment:	Not Done _____ []	Comments
5.	Start Date:	Not Done _____ //	Comments
6.	Ongoing?	Not Done _____	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS
on Jan/22/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

#	Category of Clinical Event :	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE
on Jan/22/2021

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	Not Applicable _____	Comments
2.	Subcategory of Clinical Event:	Not Applicable _____	Comments
3.	Was a diagnosis obtained?	Not Applicable _____	Comments
4.	Toxicity Grade:	Not Applicable _____	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Dec-2020 02:24

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Jan/22/2021

Form Version: 10-Dec-2020 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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[eCRF Audit Trail History](#)

Lab Chemistry Details

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

Lab Result

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

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Jan/22/2021

Form Version: 10-Dec-2020 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

5.b	Sponsor ID:	Not Applicable []	Comments
	Test:	Alanine Aminotransferase_PX30	
	Result:	Not Applicable []	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [] High [] Unit	Comments
5.c	Sponsor ID:	Not Applicable []	Comments
	Test:	Aspartate Aminotransferase_PX28	
	Result:	Not Applicable []	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [] High [] Unit	Comments

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Jan/22/2021

Form Version: 10-Dec-2020 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

5.d	Sponsor ID:	Not Applicable []	Comments
	Test:	Alkaline Phosphatase_PX35	
	Result:	Not Applicable []	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [] High [] Unit	Comments
5.e	Sponsor ID:	Not Applicable []	Comments
	Test:	Bilirubin_PX21	
	Result:	Not Applicable []	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Jan/22/2021

Form Version: 10-Dec-2020 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

5.f	Sponsor ID:	Not Applicable []	Comments
	Test:	Blood Urea Nitrogen_PX47	
	Result:	Not Applicable []	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [] High [] Unit	Comments
5.g	Sponsor ID:	Not Applicable []	Comments
	Test:	Creatinine_PX48	
	Result:	Not Applicable []	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [] High [] Unit	Comments

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Dec-2020 02:28

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Jan/22/2021

Form Version: 10-Dec-2020 02:28

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Laboratory Data Hematology

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

Lab Result

5.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Hemoglobin_PX1	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Jan/22/2021

Form Version: 10-Dec-2020 02:28

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

5.b	Sponsor ID:	Not Applicable []	Comments
	Test:	Hematocrit_PX2	
	Result:	Not Applicable []	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [] High [] Unit	Comments
5.c	Sponsor ID:	Not Applicable []	Comments
	Test:	Erythrocytes_PX3	
	Result:	Not Applicable []	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [] High [] Unit	Comments

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
on Jan/22/2021

Form Version: 10-Dec-2020 02:28

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

5.d	Sponsor ID:	Not Applicable []	Comments
	Test:	Platelets_PX5	
	Result:	Not Applicable []	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [] High [] Unit	Comments
5.e	Sponsor ID:	Not Applicable []	Comments
	Test:	Leukocytes_PX7	
	Result:	Not Applicable []	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [] High [] Unit	Comments

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
on Jan/22/2021

Form Version: 10-Dec-2020 02:28

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

5.f	Sponsor ID:	Not Applicable []	Comments
	Test:	Neutrophils_PX608	
	Result:	Not Applicable []	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [] High [] Unit	Comments
5.g	Sponsor ID:	Not Applicable []	Comments
	Test:	Eosinophils_PX609	
	Result:	Not Applicable []	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
on Jan/22/2021

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Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

5.h	Sponsor ID:	Not Applicable []	Comments
	Test:	Monocytes_PX612	
	Result:	Not Applicable []	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [] High [] Unit	Comments
5.i	Sponsor ID:	Not Applicable []	Comments
	Test:	Basophils_PX610	
	Result:	Not Applicable []	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
on Jan/22/2021

Form Version: 10-Dec-2020 02:28

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

5.j	Sponsor ID:	Not Applicable []	Comments
	Test:	Lymphocytes_PX611	
	Result:	Not Applicable []	Comments
	Not Done:	Not Applicable	Comments
	LNMT	Not Applicable Low [] High [] Unit	Comments

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 10-Dec-2020 02:25

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

#	Date:	Vital Signs Details			Form Instance
1.	Not Applicable	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		Not Applicable	Not Applicable	Not Applicable	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Jan/22/2021

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: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Vital Signs

1.	Date:	Not Applicable //	Comments
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Vital Signs Details

2.a	Record Identifier:	Not Applicable 1	
	Systolic:	Not Applicable []	Comments
	Diastolic:	Not Applicable []	Comments
	Respiratory Rate in respirations/minute:	Not Applicable []	Comments
	Heart Rate in beats/minute:	Not Applicable []	Comments

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Dec-2020 02:31

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: VITAL SIGNS - PULSE OX ROOM AIR

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

#	Date:	Vital Signs Details		Form Instance
1.	Not Applicable	Record Identifier:	Oxygen Saturation	Repeating Pages
		Not Applicable	Not Applicable	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Jan/22/2021

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: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Vital Signs

1.	Date:	Not Applicable //	Comments
----	-------	----------------------	--------------------------

Vital Signs Details

2.a	Record Identifier:	Not Applicable 1	
	SPO2 Pulse Oximetry %	Not Applicable []	Comments

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.	Not Done	Not Done	Not Done	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS
on Jan/22/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Oxygenation Parameters

1.	Date Time of Assessment:	Not Done _____ //	Comments
2.	Arterial Blood Gases PaO2 (mmHg):	Not Done _____ []	Comments
3.	FiO2 (Fraction of Inhaled Oxygen):	Not Done _____ []	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
on Jan/22/2021

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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[eCRF Audit Trail History](#)

Concomitant Medications

1.	What is the medication identifier?	Not Applicable _____ []	Comments
2.	Category:	Not Applicable _____	Comments
3.	Concomitant Medications Pre-specified:	Not Applicable _____	Comments
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).	Not Applicable _____ []	Comments
5.	Start Date:	Not Applicable _____ //	Comments
6.	Ongoing?	Not Applicable _____	Comments

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING
on Jan/22/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Imaging

1.	Date of Assessment:	Not Applicable _____ //	Comments
2.	Location of Assessment:	Not Applicable _____	Comments
3.	Type of Imaging Exam:	Not Applicable _____	Comments
4.	Assessment:	Not Applicable _____	Comments

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Feb/25/2021

Form: DATE OF VISIT - ILLNESS CONVALESCENT

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: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/25/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

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

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled
Visit on Feb/25/2021**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:** 10391337**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/25/2021
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	[BRGCFK]
5.b	Sample ID	[BRGCFL]
5.c	Sample ID	[BLBDK8]

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

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:** 10391337**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	urticaria, both hands	Feb/4/2021 UNK: UNK	NO End Date Time: Feb/6/2021 UNK:UNK	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1039

Subject No: 10391337

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): 06-Apr-2021 15:36

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[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[urticaria, both hands]
4.	Start Date Time:	Feb/4/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/6/2021 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1039

Subject No: 10391337

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): 06-Apr-2021 15:36

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	[]

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: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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Medication Error

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

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (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: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

#	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 Version: 22-Apr-2020 21:03

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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Concomitant Medications

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

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (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: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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Concomitant Medications

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

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (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: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

#	Categor y	Treatment Identifie r	Con Non-Drug Treatments Pre-specifi ed	Treatmen t	Start Dat e	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Jan/15/2021

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: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/15/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Jan/15/2021

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: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Unplanned Assessments

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

Header Text: c4591001**Visit:** Unplanned 1 - Unscheduled Visit on
Jan/15/2021**Form Version:** 22-Apr-2020 21:04**Site No:** 1039**Subject No:** 10391337**Generated By:** (b) (4)**Form:** CONTACT OUTCOME - UNPLANNED**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1039) ARC Clinical Research at Wilson Parke**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[eCRF Audit Trail History](#)**Contact Outcome**

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Jan/15/2021 Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION
3.	Comments:	[]

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1039

Subject No: 10391337

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): 06-Apr-2021 15:36

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form Version: 20-Feb-2021 02:16

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001**Visit:** Unplanned Vaccination - Unscheduled**Form:** VACCINATION**Form Version:** 10-Dec-2020 02:26**Form Status:** Not Started**Site No:** 1039**Site Name:** (1039) ARC Clinical Research at Wilson Parke**Subject No:** 10391337**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**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?	

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:** 10391337**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**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: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Contact Outcome

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1039

Subject No: 10391337

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): 06-Apr-2021 15:36

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form Version: 14-Jan-2021 02:29

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Informed Consent - Asymptomatic Surveillance

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

Header Text: c4591001**Visit:** V201_SURVEIL_CONSENT -
Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1039**Subject No:** 10391337**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Status:** Not Started**Site Name:** (1039) ARC Clinical Research at Wilson Parke**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001**Visit:** V201_SURVEIL_CONSENT -
Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1039**Subject No:** 10391337**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Status:** Not Started**Site Name:** (1039) ARC Clinical Research at Wilson Parke**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36**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: End of Treatment - Unscheduled

Form Version: 20-Feb-2021 02:26

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT

Form Status: Data Complete, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Mar/9/2021
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1039

Subject No: 10391337

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): 06-Apr-2021 15:36

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 10-Dec-2020 02:27

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Treatment Unblinded

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1039

Subject No: 10391337

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): 06-Apr-2021 15:36

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Disposition - Follow-Up

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Mar/9/2021

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
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Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[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	Mar-11-2021 12:18:26 (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.

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
Form	Jan-12-2021 13:21:05 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Jan/22/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Not Complete

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
Form	Feb-05-2021 12:30:15 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
Form	Jan-22-2021 12:12:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Jan/22/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Not Complete

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
1	Feb-05-2021 12:30:15 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
1	Jan-22-2021 12:12:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Jan/22/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Not Complete

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
2	Feb-05-2021 12:30:15 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
2	Jan-22-2021 12:12:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Jan/22/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Not Complete

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
3	Feb-05-2021 12:30:15 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
3	Jan-22-2021 12:12:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Jan/22/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Not Complete

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
4	Feb-05-2021 12:30:15 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
4	Jan-22-2021 12:12:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Jan/22/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Not Complete

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
5	Feb-05-2021 12:30:15 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
5	Jan-22-2021 12:12:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Jan/22/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Not Complete

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
6	Feb-05-2021 12:30:15 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
6	Jan-22-2021 12:12:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Jan/22/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Not Complete

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
7	Feb-05-2021 12:30:15 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
7	Jan-22-2021 12:12:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Jan/22/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Not Complete

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
8	Feb-05-2021 12:30:15 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
8	Jan-22-2021 12:12:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Jan/22/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Not Complete

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
9	Feb-05-2021 12:30:15 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
9	Jan-22-2021 12:12:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Jan/22/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
Form	Jan-22-2021 12:06:50 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Jan/22/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
1	Jan-22-2021 12:06:50 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Jan/22/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
2	Jan-22-2021 12:06:50 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Jan/22/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
3	Jan-22-2021 12:06:50 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Jan/22/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

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Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
4	Jan-22-2021 12:06:50 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Jan/22/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
5	Jan-22-2021 12:06:50 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Jan/22/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
6	Jan-22-2021 12:06:50 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
on Jan/22/2021

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
Form	Jan-22-2021 12:07:37 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
on Jan/22/2021

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
1	Jan-22-2021 12:07:37 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
on Jan/22/2021

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

[Back to Form](#)

Item	Date	User	Comment
2	Jan-22-2021 12:07:37 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
on Jan/22/2021

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

[Back to Form](#)

Item	Date	User	Comment
3	Jan-22-2021 12:07:37 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
on Jan/22/2021

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
4	Jan-22-2021 12:07:37 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Jan/22/2021

Form Version: 10-Dec-2020 02:24

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY -
Comments

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Jan/22/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY -
Comments

Form Version: 10-Dec-2020 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
1	Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Jan/22/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY -
Comments

Form Version: 10-Dec-2020 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

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Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
2	Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Jan/22/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY -
Comments

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Item	Date	User	Comment
3	Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
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Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY -
Comments

Form Version: 10-Dec-2020 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
4	Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/22/2021**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments**Form Version:** 10-Dec-2020 02:24**Form Status:** Data Complete, Frozen, Verified**Site No:** 1039**Site Name:** (1039) ARC Clinical Research at Wilson Parke**Subject No:** 10391337**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)

Item	Date	User	Comment
5.a	Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Jan/22/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY -
Comments

Form Version: 10-Dec-2020 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
5.a	Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Jan/22/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY -
Comments

Form Version: 10-Dec-2020 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
5.a	Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Jan/22/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY -
Comments

Form Version: 10-Dec-2020 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

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Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
5.a	Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/22/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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Site No: 1039

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5.b	Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

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Header Text: c4591001

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2.a	Jan-22-2021 12:09:50 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments
on Jan/22/2021

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: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
Form	Jan-22-2021 12:11:42 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments
on Jan/22/2021

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: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
1	Jan-22-2021 12:11:42 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments
on Jan/22/2021

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: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
2.a	Jan-22-2021 12:11:42 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments
on Jan/22/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
Form	Jan-22-2021 12:11:53 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments
on Jan/22/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
1	Jan-22-2021 12:11:53 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments
on Jan/22/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
2	Jan-22-2021 12:11:53 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments
on Jan/22/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
3	Jan-22-2021 12:11:53 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Jan/22/2021

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS -
Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
Form	Jan-22-2021 12:05:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Jan/22/2021

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS -
Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
1	Jan-22-2021 12:05:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Jan/22/2021

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS -
Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
2	Jan-22-2021 12:05:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Jan/22/2021

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS -
Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
3	Jan-22-2021 12:05:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Jan/22/2021

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS -
Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
4	Jan-22-2021 12:05:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Jan/22/2021

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS -
Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
5	Jan-22-2021 12:05:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Jan/22/2021

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS -
Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
6	Jan-22-2021 12:05:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Jan/22/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
Form	Jan-22-2021 12:05:24 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Jan/22/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
1	Jan-22-2021 12:05:24 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Jan/22/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
2	Jan-22-2021 12:05:24 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Jan/22/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
3	Jan-22-2021 12:05:24 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Jan/22/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Item	Date	User	Comment
4	Jan-22-2021 12:05:24 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1039

Subject No: 10391337

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): 06-Apr-2021 15:36

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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	Mar-11-2021 12:18:26 (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.

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 10-Dec-2020 02:31

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: COHORT SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Jan-12-2021 13:19:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(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
Jan-12-2021 13:19:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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I. Consent Was:

Date	Location	User	Value	Reason
Jan-12-2021 13:20:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Jan/12/2021	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 10-Dec-2020 02:26

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Subject ID

Date	Location	User	Value	Reason
Jan-12-2021 13:16:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10391337	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Jan-12-2021 13:15:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 2005	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Jan-12-2021 13:20:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Jan-12-2021 13:20:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Jan-12-2021 13:20:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

6. Racial Designation:

Date	Location	User	Value	Reason
Jan-22-2021 00:00:35	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo	Response satisfies query

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001**Visit:** COHORT_SELECTION**Form Version:** 10-Dec-2020 02:26**Site No:** 1039**Subject No:** 10391337**Generated By:** (b) (4)**Form:** DEMOGRAPHY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1039) ARC Clinical Research at Wilson Parke**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36

(UTC-06:00) Central Time (US & Canada)			sed	
Jan-21-2021 20:39:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Clo sed	Auto closed by Validation Check: VC_DM001_09
Jan-21-2021 12:15:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: An swere d	Changed Information
Jan-21-2021 12:15:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: An swere d	Changed Information
Jan-21-2021 12:15:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry :	Changed Information
Jan-21-2021 10:57:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Op ened	DMW6938127;Racial Designation is updated, however Race is not ASIAN. Please review and update appropriately or clarify.
Jan-21-2021 09:49:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW6938127;Racial Designation is updated, however Race is not ASIAN. Please review and update appropriately or clarify.

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 10-Dec-2020 02:26

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Jan-12-2021 13:20:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry : OTH ER	Initial Entry
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1039

Subject No: 10391337

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): 06-Apr-2021 15:36

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-12-2021 13:20:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/12/2021	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Jan-12-2021 13:21:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/12/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-12-2021 13:21:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-12-2021 13:21:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1039**Subject No:** 10391337**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1039) ARC Clinical Research at Wilson Parke**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**I.a**

Date	Location	User	Value	Reason
Jan-12-2021 13:24:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 1 : Medical History T penicillin alle erm: rgy Start Date: UNK/UNK/2 007 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Jan-12-2021 13:24:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Jan-21-2021 23:45:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-21-2021 13:48:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Jan-20-2021 14:53:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Please add intermittent diarrhea to subject's medhx.
Jan-12-2021 13:24:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: penicillin allergy	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
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Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1039**Subject No:** 10391337**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1039) ARC Clinical Research at Wilson Parke**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36

Jan-12-2021 13:24:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2007	Initial Entry
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1.a Ongoing:

Date	Location	User	Value	Reason
Jan-12-2021 13:24:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Jan-12-2021 13:25:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 2 : Medical History T acne erm: Start Date: UNK/UNK/2 018 Ongoing: YES	Initial Entry

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1039**Subject No:** 10391337**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1039) ARC Clinical Research at Wilson Parke**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36***1.b Line/MH Number:***

Date	Location	User	Value	Reason
Jan-12-2021 13:25:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Jan-12-2021 13:25:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: acne	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Jan-12-2021 13:25:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2018	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Jan-12-2021 13:25:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Jan-12-2021 13:27:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History eczema, bilatera Term: 1 arms Start Date: UNK/UNK/201 2	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

			Ongoing: NO End Date: UNK/UNK/2012	
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1.c Line/MH Number:

Date	Location	User	Value	Reason
Jan-12-2021 13:27:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Jan-12-2021 13:27:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: eczema, bilateral arms	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Jan-12-2021 13:27:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2012	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
Jan-12-2021 13:27:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2012	Initial Entry

1.d

Date	Location	User	Value	Reason
Jan-12-2021 13:27:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number:	Initial Entry

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

			Medical History Term:	tonsillectomy
			Start Date:	UNK/UNK/2011
			Ongoing:	NO
			End Date:	UNK/UNK/2011

1.d Line/MH Number:

Date	Location	User	Value	Reason
Jan-12-2021 13:27:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Jan-12-2021 13:27:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: tonsillectomy	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Jan-12-2021 13:27:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2011	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Jan-12-2021 13:27:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2011	Initial Entry

1.e

Date	Location	User	Value	Reason
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090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1039**Subject No:** 10391337**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1039) ARC Clinical Research at Wilson Parke**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36

Jan-21-2021 13:48:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 5 : Medical History T recurrent diarr erm: hea Start Date: UNK/UNK/2 010 Ongoing: YES	Initial Entry
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1.e Line/MH Number:

Date	Location	User	Value	Reason
Jan-21-2021 13:48:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Jan-21-2021 13:48:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: recurrent diarrhea	Initial Entry

1.e Start Date:

Date	Location	User	Value	Reason
Jan-21-2021 13:48:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

1.e Ongoing:

Date	Location	User	Value	Reason
Jan-21-2021 13:48:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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

Date	Location	User	Value	Reason
Jan-12-2021 13:21:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: The subject is NOT known to be HIV POSITIVE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:29

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Date:

Date	Location	User	Value	Reason
Jan-12-2021 13:22:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/12/2021	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Jan-12-2021 13:22:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 84.7	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Jan-12-2021 13:22:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Jan-12-2021 13:22:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 182.4	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Jan-12-2021 13:22:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Jan-12-2021 13:22:05 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 25.5	Initial Entry

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:29

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Time (US & Canada)

7.a

Date	Location	User	Value	Reason
Jan-12-2021 13:22:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: 1 : Temperature: 36.8 Temperature Unit C : Temperature Location: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Jan-12-2021 13:22:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Jan-12-2021 13:22:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.8	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Jan-12-2021 13:22:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Jan-12-2021 13:22:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Randomization Date :

Date	Location	User	Value	Reason
Jan-12-2021 13:22:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/12/2021	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Jan-12-2021 13:22:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 26822	Initial Entry

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Data Origin

Date	Location	User	Value	Reason
Jan-12-2021 13:22:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-12-2021 13:22:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-13-2021 07:48:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-13-2021 05:08:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-12-2021 13:22:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-12-2021 13:22:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/12/2021	Initial Entry

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

5.a

Date	Location	User	Value	Reason
Jan-13-2021 07:48:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRJBTF	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-13-2021 07:48:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRJBTF	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-13-2021 07:48:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRJBTF	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-13-2021 07:48:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRJBTF	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-13-2021 07:48:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BS6HBS	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-13-2021 07:48:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BS6HBS	Initial Entry

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1039**Subject No:** 10391337**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL 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):** 06-Apr-2021 15:36[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-12-2021 13:23:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-12-2021 13:23:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-13-2021 07:29:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-13-2021 05:08:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-12-2021 13:23:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-12-2021 13:23:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/12/2021	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL 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): 06-Apr-2021 15:36

5.a

Date	Location	User	Value	Reason
Jan-13-2021 07:29:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Sample ID: BRJBCH	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-13-2021 07:29:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: BRJBCH	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:26

Site No: 1039

Subject No: 10391337

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): 06-Apr-2021 15:36

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-12-2021 13:23:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-12-2021 13:23:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-12-2021 13:23:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jan-12-2021 13:23:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/12/2021 12:09	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-12-2021 13:23:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-12-2021 13:23:52 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Dec-2020 02:26

Site No: 1039

Subject No: 10391337

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): 06-Apr-2021 15:36

Time (US & Canada)

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

7. Route:

Date	Location	User	Value	Reason
Jan-12-2021 13:23:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-12-2021 13:23:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Jan-12-2021 13:23:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Jan-12-2021 13:24:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES - REACTOGENICITY E-D IARY COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1039

Subject No: 10391337

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): 06-Apr-2021 15:36

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-03-2021 10:24:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/3/2021	Initial Entry

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 10-Dec-2020 02:30**Site No:** 1039**Subject No:** 10391337**Generated By:** (b) (4)**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1039) ARC Clinical Research at Wilson Parke**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Feb-03-2021 10:37:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Feb-03-2021 10:37:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FE VE R Were fever or systemic sy N mptoms present on the las O t day the Subject Diary wa s completed?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Feb-03-2021 10:37:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Feb-03-2021 10:37:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Feb-03-2021 10:37:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

			GU E Were fever or systemic sy NO mptoms present on the las t day the Subject Diary w as completed?:	
--	--	--	---	--

2.b Symptom:

Date	Location	User	Value	Reason
Feb-03-2021 10:37:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<u>Data Entry:</u> 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-03-2021 10:37:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Feb-03-2021 10:37:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<u>Data Entry:</u> Symptom:: HE AD AC HE Were fever or systemic sy NO mptoms present on the la st day the Subject Diary was completed?:	Initial Entry

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

2.c Symptom:

Date	Location	User	Value	Reason
Feb-03-2021 10:37:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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-03-2021 10:37:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Feb-03-2021 10:37:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: CH IL LS Were fever or systemic sy NO mptoms present on the las t day the Subject Diary wa s completed?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Feb-03-2021 10:37:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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-03-2021 10:37:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.e

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Feb-03-2021 10:37:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Symptom:: VO MIT ING Were fever or systemic sy NO mptoms present on the la st day the Subject Diary was completed?:	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Feb-03-2021 10:37:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	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-03-2021 10:37:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Feb-03-2021 10:37:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Symptom:: DIA RR HE A Were fever or systemic sy NO mptoms present on the la st day the Subject Diary was completed?:	Initial Entry

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

2.f Symptom:

Date	Location	User	Value	Reason
Feb-03-2021 10:37:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(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-03-2021 10:37:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Feb-03-2021 10:37:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED MU SCLE PA IN Were fever or syste NO mic symptoms prese nt on the last day th e Subject Diary was completed?:	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Feb-03-2021 10:37:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENER MUSCL E 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-03-2021 10:37:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

2.h

Date	Location	User	Value	Reason
Feb-03-2021 10:37:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED JOI NT PAIN Were fever or syste NO mic symptoms prese nt on the last day the Subject Diary was c ompleted?:	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Feb-03-2021 10:37:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSE NED JOI NT 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-03-2021 10:37:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Feb-03-2021 10:37:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Feb-03-2021 10:37:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

5.a

Date	Location	User	Value	Reason
Feb-03-2021 10:37:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reacti NO ons present on the last da y the Subject Diary was c ompleted?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Feb-03-2021 10:37:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Feb-03-2021 10:37:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-03-2021 10:37:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SW ELL ING Were injection site reacti NO ons present on the last d ay the Subject Diary was completed?:	Initial Entry

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Feb-03-2021 10:37:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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-03-2021 10:37:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-03-2021 10:37:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Feb-03-2021 10:37:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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-03-2021 10:37:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196b72783\Final\On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 14-Jan-2021 02:22**Site No:** 1039**Subject No:** 10391337**Generated By:** (b) (4)**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1039) ARC Clinical Research at Wilson Parke**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Feb-03-2021 10:38:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Feb/3/2021	Initial Entry

2.a

Date	Location	User	Value	Reason
Feb-03-2021 10:38:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Record Identifier: 1 : Temperature: 36.6 Temperature Unit C : Temperature Loc ORAL CAV ation:: ITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Feb-03-2021 10:38:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Feb-03-2021 10:38:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: 36.6	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Feb-03-2021 10:38:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: C	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 14-Jan-2021 02:22

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

2.a Temperature Location:

Date	Location	User	Value	Reason
Feb-03-2021 10:38:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL 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): 06-Apr-2021 15:36

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1. Data Origin

Date	Location	User	Value	Reason
Feb-03-2021 10:38:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-03-2021 10:38:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-03-2021 13:21:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-03-2021 10:38:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-03-2021 10:38:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/3/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-03-2021 13:21:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRMFPK	Initial Entry

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL 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): 06-Apr-2021 15:36

5.a Sample ID

Date	Location	User	Value	Reason
Feb-03-2021 13:21:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<u>Data Entry:</u> BRMFPPK	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1039

Subject No: 10391337

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): 06-Apr-2021 15:36

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-03-2021 10:39:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-03-2021 10:39:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-03-2021 10:39:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Feb-03-2021 10:39:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/3/2021 07:51	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-03-2021 10:39:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Feb-03-2021 10:39:07 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1039

Subject No: 10391337

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): 06-Apr-2021 15:36

Time (US & Canada)

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

7. Route:

Date	Location	User	Value	Reason
Feb-03-2021 10:39:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-03-2021 10:39:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Feb-03-2021 10:39:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1039

Subject No: 10391337

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): 06-Apr-2021 15:36

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-10-2021 14:04:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-10-2021 11:31:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Mar-10-2021 02:32:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The treatment period is defined as 1st vaccination visit through the 1-month post vaccination visit after the 2nd vaccination. Please complete treatment disposition CRF and update date of EOT to match date of visit at visit 3.
Mar-09-2021 09:13:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/9/2021	Initial Entry

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form Version:** 10-Dec-2020 02:30**Site No:** 1039**Subject No:** 10391337**Generated By:** (b) (4)**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1039) ARC Clinical Research at Wilson Parke**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Mar-09-2021 09:15:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Mar-09-2021 09:15:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FE VE R Were fever or systemic sy N mptoms present on the las O t day the Subject Diary wa s completed?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Mar-09-2021 09:15:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Mar-09-2021 09:15:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Mar-09-2021 09:15:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

			GU E Were fever or systemic sy NO mptoms present on the las t day the Subject Diary w as completed?:	
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2.b Symptom:

Date	Location	User	Value	Reason
Mar-09-2021 09:15:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	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
Mar-09-2021 09:15:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Mar-09-2021 09:15:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Symptom:: HE AD AC HE Were fever or systemic s NO ymptoms present on the l ast day the Subject Diary was completed?:	Initial Entry

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (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, Frozen, Verified**Site No:** 1039**Site Name:** (1039) ARC Clinical Research at Wilson Parke**Subject No:** 10391337**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36**2.c Symptom:**

Date	Location	User	Value	Reason
Mar-09-2021 09:15:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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
Mar-09-2021 09:15:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Mar-09-2021 09:15:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: CH IL LS Were fever or systemic sy NO mptoms present on the las t day the Subject Diary w as completed?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Mar-09-2021 09:15:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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
Mar-09-2021 09:15:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.e

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Mar-09-2021 09:15:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MIT ING Were fever or systemic s NO ymptoms present on the l ast day the Subject Diary was completed?:	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Mar-09-2021 09:15:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(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
Mar-09-2021 09:15:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Mar-09-2021 09:15:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic sy NO mptoms present on the la st day the Subject Diary was completed?:	Initial Entry

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form Version:** 10-Dec-2020 02:30**Site No:** 1039**Subject No:** 10391337**Generated By:** (b) (4)**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1039) ARC Clinical Research at Wilson Parke**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36**2.f Symptom:**

Date	Location	User	Value	Reason
Mar-09-2021 09:15:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(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
Mar-09-2021 09:15:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Mar-09-2021 09:15:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED MU SCLE PA IN Were fever or syste NO mic symptoms prese nt on the last day th e Subject Diary was completed?:	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Mar-09-2021 09:15:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSE NED 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
Mar-09-2021 09:15:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

2.h

Date	Location	User	Value	Reason
Mar-09-2021 09:15:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Symptom:: NEW O R WORS ENED J OINT PA IN Were fever or syste mic symptoms prese nt on the last day th e Subject Diary was completed?: NO	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Mar-09-2021 09:15:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NEW OR WORSENERD 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
Mar-09-2021 09:15:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Mar-09-2021 09:15:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Mar-09-2021 09:15:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: LEFT	Initial Entry

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

5.a

Date	Location	User	Value	Reason
Mar-09-2021 09:15:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reacti NO ons present on the last da y the Subject Diary was c ompleted?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Mar-09-2021 09:15:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Mar-09-2021 09:15:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-09-2021 09:15:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SW ELL ING Were injection site reacti NO ons present on the last d ay the Subject Diary was completed?:	Initial Entry

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 10-Dec-2020 02:30

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Mar-09-2021 09:15:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Mar-09-2021 09:15:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-09-2021 09:15:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Mar-09-2021 09:15:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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
Mar-09-2021 09:15:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196b72783\Final\On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Data Origin

Date	Location	User	Value	Reason
Mar-09-2021 09:16:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-09-2021 09:16:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-09-2021 14:51:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-09-2021 09:16:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-09-2021 09:16:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/9/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-09-2021 14:51:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRGCHR	Initial Entry

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

5.a Sample ID

Date	Location	User	Value	Reason
Mar-09-2021 14:51:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<u>Data Entry:</u> BRGCHR	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-09-2021 14:51:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<u>Data Entry:</u> Sample ID: BRGCHS	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-09-2021 14:51:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<u>Data Entry:</u> BRGCHS	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-09-2021 14:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<u>Data Entry:</u> Sample ID: BLBDLF	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-09-2021 14:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<u>Data Entry:</u> BLBDLF	Initial Entry

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Jan/22/2021**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:** 10391337**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Date of Visit**

Date	Location	User	Value	Reason
Jan-22-2021 12:06:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-22-2021 12:04:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Jan-22-2021 12:04:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Jan-22-2021 12:04:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Jan-22-2021 12:04:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/22/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Jan-22-2021 12:04:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Jan/22/2021

Form Version: 14-Jan-2021 02:23

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Date of Assessment:

Date	Location	User	Value	Reason
Jan-22-2021 12:04:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-22-2021 12:04:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	All symptoms are reported as Not Present and there is no Other Symptom reported. Please review and update as appropriate.
Jan-22-2021 12:04:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/22/2021	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Jan-22-2021 12:04:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/22/2021	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Feb-12-2021 08:04:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-05-2021 12:30:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Feb-05-2021 12:30:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolve d:	Changed Information

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit
on Jan/22/2021**Form Version:** 14-Jan-2021 02:23**Site No:** 1039**Subject No:** 10391337**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1039) ARC Clinical Research at Wilson Parke**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36

			Jan/24/2021	
Feb-05-2021 02:46:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Please reconcile. Per source documents, symptoms resolved 24Jan2021. Please update as appropriate.
Jan-22-2021 12:04:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Jan-22-2021 12:04:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Jan-22-2021 12:04:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Jan-22-2021 12:04:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Jan-22-2021 12:04:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREA SED COUGH	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Jan/22/2021

Form Version: 14-Jan-2021 02:23

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

			Symptom NO Present:	
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4.b Symptoms:

Date	Location	User	Value	Reason
Jan-22-2021 12:04:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Jan-22-2021 12:04:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Jan-22-2021 12:04:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: NO	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Jan-22-2021 12:04:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Jan-22-2021 12:04:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Jan/22/2021

Form Version: 14-Jan-2021 02:23

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

4.d

Date	Location	User	Value	Reason
Jan-22-2021 12:04:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Jan-22-2021 12:04:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Jan-22-2021 12:04:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Jan-22-2021 12:04:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCREAS s: ED MUSCLE PAIN Symptom NO Present:	Initial Entry

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Jan/22/2021

Form Version: 14-Jan-2021 02:23

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

4.e Symptoms:

Date	Location	User	Value	Reason
Jan-22-2021 12:04:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Jan-22-2021 12:04:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Jan-22-2021 12:04:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms NEW LOSS OF TASTE OR SMELL Symptom NO Present:	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Jan-22-2021 12:04:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Jan-22-2021 12:04:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Jan-22-2021 12:04:46	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/22/2021

Form Version: 14-Jan-2021 02:23

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	Symptom NEW OR INCREASED SORE THROAT Symptom NO Present:	
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4.g Symptoms:

Date	Location	User	Value	Reason
Jan-22-2021 12:04:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Jan-22-2021 12:04:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Jan-22-2021 12:04:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHEA Symptom Present NO :	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Jan-22-2021 12:04:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Jan-22-2021 12:04:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/22/2021**Form Version:** 14-Jan-2021 02:23**Site No:** 1039**Subject No:** 10391337**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1039) ARC Clinical Research at Wilson Parke**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36**4.i**

Date	Location	User	Value	Reason
Jan-22-2021 12:04:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMITING Symptom Present: NO	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Jan-22-2021 12:04:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Jan-22-2021 12:04:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-22-2021 12:04:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other: nausea	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Jan-22-2021 12:04:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: nausea	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-22-2021 12:05:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other: erythema, left petoral	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Jan/22/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

5.b Symptoms - Other Text:

Date	Location	User	Value	Reason
Jan-22-2021 12:05:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: erythema, left pectoral	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Audit Trail
on Jan/22/2021

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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Date	Location	User	Value	Reason
Feb-05-2021 12:34:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
on Jan/22/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Not Complete

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Feb-12-2021 08:05:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-05-2021 12:34:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Feb-05-2021 12:34:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/23/2021	Initial Entry
Feb-05-2021 12:30:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Feb-05-2021 02:47:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Please reconcile. Per source documents, subject received Covid test on 23Jan2021. Please update as appropriate.
Jan-22-2021 12:12:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Feb-05-2021 12:34:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWABBED MATERIAL	Initial Entry
Feb-05-2021 12:30:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Jan-22-2021 12:12:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
on Jan/22/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Not Complete

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Feb-05-2021 12:34:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NASOPHARYNX	Initial Entry
Feb-05-2021 12:30:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Jan-22-2021 12:12:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Feb-05-2021 12:34:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYND ROME CORONAVIRUS 2	Initial Entry
Feb-05-2021 12:30:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Jan-22-2021 12:12:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Feb-05-2021 12:34:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TE ST	Initial Entry
Feb-05-2021 12:30:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Jan-22-2021 12:12:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196b72783\Final\On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
on Jan/22/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Not Complete

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

6. Trade Name:

Date	Location	User	Value	Reason
Feb-05-2021 12:34:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry
Feb-05-2021 12:30:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Jan-22-2021 12:12:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Feb-05-2021 12:34:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry
Feb-05-2021 12:30:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Jan-22-2021 12:12:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Feb-05-2021 12:30:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Jan-22-2021 12:12:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
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090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Jan/22/2021**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1039**Site Name:** (1039) ARC Clinical Research at Wilson Parke**Subject No:** 10391337**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36

Feb-25-2021 13:43:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	data updated
Feb-25-2021 13:43:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	error
Feb-25-2021 13:43:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	data updated
Feb-25-2021 08:18:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Feb-25-2021 08:18:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Curative- Korva S ARS-Co v-2 Assa y	Changed Information
Feb-25-2021 04:15:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM2: As per FDA List of Trade names and CRF CR, data should be updated as Curative-Korva SARS-Cov-2 Assay, Kindly confirm and update data as

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
on Jan/22/2021**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1039**Site Name:** (1039) ARC Clinical Research at Wilson Parke**Subject No:** 10391337**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36

				requested, else clarify, Thank you.
Feb-24-2021 12:43:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Curative SARS-Cov-2 Assay	Transcription Error
Feb-24-2021 12:43:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	PER FDA WEBSITE Curative SARS-COV-2 Assay is approved for EUA.
Feb-24-2021 04:19:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM: curative sars cov2 assay korva labs inc is not indicated on the FDA cleared diagnostic list and is not indicated as CLIA certified lab or ISO 15189 accredited lab . Please verify and update as appropriate. Otherwise, please provide clarification.
Feb-23-2021 16:02:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
on Jan/22/2021**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1039**Site Name:** (1039) ARC Clinical Research at Wilson Parke**Subject No:** 10391337**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36

Feb-23-2021 16:02:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Curative SARS-C OV2 Ass ay	Transcription Error
Feb-08-2021 05:03:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	curative sars cov2 assay korva labs inc is not indicated on the FDA cleared (including Emergency Use Authorization) diagnostic list and is not indicated as CLIA certified lab or ISO 15189 accredited lab . Please verify and update as appropriate. Otherwise, please provide clarification. (b) (4)
Feb-05-2021 12:34:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Curative SARS-C OV2 Ass ay Korva Labs Inc	Initial Entry
Feb-05-2021 12:30:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
on Jan/22/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Not Complete

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Jan-22-2021 12:12:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Done	Initial Entry
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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/22/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1039**Subject No:** 10391337**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1039) ARC Clinical Research at Wilson Parke**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-22-2021 12:06:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-22-2021 12:06:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-25-2021 11:50:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-25-2021 10:26:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-22-2021 12:06:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-22-2021 12:06:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/22/2021	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Jan/22/2021

Form Version: 22-Apr-2020 21:03

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

5.a

Date	Location	User	Value	Reason
Jan-25-2021 11:50:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: RR10921	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-25-2021 11:50:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RR10921	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Jan/22/2021

Form Version: 22-Apr-2020 21:03

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL 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): 06-Apr-2021 15:36

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1. Data Origin

Date	Location	User	Value	Reason
Jan-22-2021 12:06:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-22-2021 12:06:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-22-2021 12:06:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Jan-22-2021 12:06:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Patient will collect self swab.	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
on Jan/22/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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1.a

Date	Location	User	Value	Reason
Jan-22-2021 12:06:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

1.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-22-2021 12:06:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

1.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-22-2021 12:06:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.b

Date	Location	User	Value	Reason
Jan-22-2021 12:06:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: NO	Initial Entry

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/22/2021**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete, Frozen, Verified**Site No:** 1039**Site Name:** (1039) ARC Clinical Research at Wilson Parke**Subject No:** 10391337**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36***I.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-22-2021 12:06:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

I.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-22-2021 12:06:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.c

Date	Location	User	Value	Reason
Jan-22-2021 12:06:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

I.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-22-2021 12:06:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-22-2021 12:06:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.d

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/22/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Jan-22-2021 12:06:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner URGENT : Occurrence of Visit NO s or Contacts:	Initial Entry
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1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-22-2021 12:06:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-22-2021 12:06:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Jan-22-2021 12:06:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO	Initial Entry

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
on Jan/22/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

1.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-22-2021 12:06:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-22-2021 12:06:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.f

Date	Location	User	Value	Reason
Jan-22-2021 12:06:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTH ER Occurrence of Visits or Contacts: NO	Initial Entry

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-22-2021 12:06:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-22-2021 12:06:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-22-2021 12:06:31	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
on Jan/22/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	NO	
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090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History
on Jan/22/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Jan-22-2021 12:06:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Jan-22-2021 12:06:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Jan-22-2021 12:06:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Jan-22-2021 12:06:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Jan-22-2021 12:06:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
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090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History on Jan/22/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Jan-22-2021 12:06:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History
on Jan/22/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Jan-22-2021 12:07:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNES S	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Jan-22-2021 12:07:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-22-2021 12:07:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History on Jan/22/2021

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Jan-22-2021 12:07:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Jan-22-2021 12:07:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Jan-22-2021 12:07:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-22-2021 12:07:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/22/2021**Form Version:** 10-Dec-2020 02:24**Site No:** 1039**Subject No:** 10391337**Generated By:** (b) (4)**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1039) ARC Clinical Research at Wilson Parke**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable entifier: Test:: Not Applicable Result:: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/22/2021

Form Version: 10-Dec-2020 02:24

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

			Not Done::	Not Applicable	
			Lab Normal Range	Not Applicable	
			:		

5.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Jan/22/2021

Form Version: 10-Dec-2020 02:24

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY -
eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range Not Applicable : able	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/22/2021

Form Version: 10-Dec-2020 02:24

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

5.b Sponsor ID:

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable entifier: able	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/22/2021

Form Version: 10-Dec-2020 02:24

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range	Not Applicable	
			:		

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/22/2021

Form Version: 10-Dec-2020 02:24

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

5.c Sponsor ID:

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable entifier: able	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/22/2021

Form Version: 10-Dec-2020 02:24

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range	Not Applicable	
			:		

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/22/2021

Form Version: 10-Dec-2020 02:24

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

5.d Sponsor ID:

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable entifier: able	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Jan/22/2021

Form Version: 10-Dec-2020 02:24

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY -
eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range	Not Applicable	
			:		

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/22/2021

Form Version: 10-Dec-2020 02:24

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

5.e Sponsor ID:

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable entifier: able	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/22/2021

Form Version: 10-Dec-2020 02:24

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range	Not Applicable	
			:		

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/22/2021

Form Version: 10-Dec-2020 02:24

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

5.f Sponsor ID:

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable entifier: able	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/22/2021

Form Version: 10-Dec-2020 02:24

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range	Not Applicable	
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Jan/22/2021

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

Subject Initials: ---

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5.g Sponsor ID:

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Jan-22-2021 12:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/22/2021**Form Version:** 10-Dec-2020 02:28**Site No:** 1039**Subject No:** 10391337**Generated By:** (b) (4)**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1039) ARC Clinical Research at Wilson Parke**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable entifier: Test:: Not Applicable Result:: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/22/2021

Form Version: 10-Dec-2020 02:28

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

			Not Done::	Not Applicable	
			Lab Normal Range	Not Applicable	
			:		

5.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Jan/22/2021

Form Version: 10-Dec-2020 02:28

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology -
eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range Not Applicable : applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/22/2021

Form Version: 10-Dec-2020 02:28

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

5.b Sponsor ID:

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable entifier: able	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/22/2021

Form Version: 10-Dec-2020 02:28

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range	Not Applicable	
			:		

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/22/2021

Form Version: 10-Dec-2020 02:28

Site No: 1039

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Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

5.c Sponsor ID:

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable entifier: able	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/22/2021

Form Version: 10-Dec-2020 02:28

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range	Not Applicable	
			:		

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5.d Sponsor ID:

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable entifier: able	Initial Entry

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			Test::	Not Applicable	
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Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable entifier: able	Initial Entry

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			Not Done::	Not Applicable	
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5.g Sponsor ID:

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable entifier: able	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/22/2021

Form Version: 10-Dec-2020 02:28

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range	Not Applicable	
			:		

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/22/2021

Form Version: 10-Dec-2020 02:28

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

5.h Sponsor ID:

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable entifier: able	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/22/2021

Form Version: 10-Dec-2020 02:28

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range	Not Applicable	
			:		

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Jan/22/2021

Form Version: 10-Dec-2020 02:28

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology -
eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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5.i Sponsor ID:

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i Not Done:

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applic	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/22/2021

Form Version: 10-Dec-2020 02:28

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Time (US & Canada)		(b) (4), (b) (6)	entifier:	able	
			Test::	Not Applic able	
			Result::	Not Applic able	
			Not Done::	Not Applic able	
			Lab Normal Range	Not Applic	
			:	able	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Jan/22/2021

Form Version: 10-Dec-2020 02:28

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology -
eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

5.j Sponsor ID:

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Jan-22-2021 12:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History on Jan/22/2021**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:** 10391337**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Jan-22-2021 12:09:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-22-2021 12:09:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Not Applicable Systolic:: Not Applicable Diastolic:: Not Applicable Respiratory Rate in respirations/minute: Not Applicable Heart Rate in beats/minute: Not Applicable	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-22-2021 12:09:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Jan-22-2021 12:09:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History
on Jan/22/2021

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: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

Jan-22-2021 12:09:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Jan-22-2021 12:09:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Jan-22-2021 12:09:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/22/2021**Form Version:** 10-Dec-2020 02:31**Site No:** 1039**Subject No:** 10391337**Generated By:** (b) (4)**Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1039) ARC Clinical Research at Wilson Parke**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Jan-22-2021 12:11:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-22-2021 12:11:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier Not Applicab :: le Oxygen Saturati Not Applicab on: le	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-22-2021 12:11:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Jan-22-2021 12:11:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History
on Jan/22/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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1. Date Time of Assessment:

Date	Location	User	Value	Reason
Jan-22-2021 12:11:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Arterial Blood Gases PaO2 (mmHg):

Date	Location	User	Value	Reason
Jan-22-2021 12:11:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. FiO2 (Fraction of Inhaled Oxygen):

Date	Location	User	Value	Reason
Jan-22-2021 12:11:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit
on Jan/22/2021**Form Version:** 06-Jul-2020 21:55**Site No:** 1039**Subject No:** 10391337**Generated By:** (b) (4)**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF
Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1039) ARC Clinical Research at Wilson Parke**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Jan-22-2021 12:05:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jan-22-2021 12:05:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jan-22-2021 12:05:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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).

Date	Location	User	Value	Reason
Jan-22-2021 12:05:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Jan-22-2021 12:05:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Jan/22/2021

Form Version: 06-Jul-2020 21:55

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF
Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

6. Ongoing?

Date	Location	User	Value	Reason
Jan-22-2021 12:05:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - eCRF Audit Trail History
on Jan/22/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1039

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

Subject No: 10391337

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 06-Apr-2021 15:36

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1. Date of Assessment:

Date	Location	User	Value	Reason
Jan-22-2021 12:05:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Jan-22-2021 12:05:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Jan-22-2021 12:05:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Jan-22-2021 12:05:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196b72783\Final\On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Feb/25/2021

Form Version: 22-Apr-2020 21:04

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit
Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-25-2021 08:19:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/25/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Feb-25-2021 08:19:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_A1	Initial Entry

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled
Visit on Feb/25/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1039**Subject No:** 10391337**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1039) ARC Clinical Research at Wilson Parke**Subject Initials:** ---**Generated Time (GMT):** 06-Apr-2021 15:36[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-25-2021 08:23:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-25-2021 08:23:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-25-2021 14:59:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-25-2021 08:23:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-25-2021 08:23:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: YES Date of Collection: Feb/25/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-25-2021 14:59:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Sample ID: BRGCFK	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Feb/25/2021

Form Version: 22-Apr-2020 21:03

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

5.a Sample ID

Date	Location	User	Value	Reason
Feb-25-2021 14:59:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<u>Data Entry:</u> BRGCFK	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-25-2021 15:00:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<u>Data Entry:</u> Sample ID: BRGCFL	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-25-2021 15:00:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<u>Data Entry:</u> BRGCFL	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-25-2021 15:02:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<u>Data Entry:</u> Sample ID: BLBDK8	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-25-2021 15:02:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<u>Data Entry:</u> BLBDK8	Initial Entry

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1039

Subject No: 10391337

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): 06-Apr-2021 15:36

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Date	Location	User	Value	Reason
Feb-04-2021 11:57:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Category:

Date	Location	User	Value	Reason
Feb-04-2021 11:57:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-04-2021 11:57:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-04-2021 11:57:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: urticaria, both hands	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-04-2021 11:57:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/4/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-09-2021 13:32:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Feb/6/2021 UNK:UNK	Changed Information
Feb-04-2021 11:57:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-04-2021 11:57:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-04-2021 11:57:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Feb-04-2021 11:57:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-04-2021 11:57:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-04-2021 11:57:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

Date	Location	User	Value	Reason
Feb-04-2021 11:57:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-04-2021 11:57:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-09-2021 13:32:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-09-2021 13:32:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Changed Information
Feb-09-2021 13:32:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE urticaria, both hands: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Feb-04-2021 11:57:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Feb-04-2021 11:57:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Jan/15/2021

Form Version: 22-Apr-2020 21:02

Site No: 1039

Subject No: 10391337

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): 06-Apr-2021 15:36

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-19-2021 13:55:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Jan/15/2021	Transcription Error
Jan-19-2021 13:55:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Jan/12/2021	Initial Entry

Header Text: c4591001**Visit:** Unplanned 1 - Unscheduled Visit on
Jan/15/2021**Form Version:** 22-Apr-2020 21:04**Site No:** 1039**Subject No:** 10391337**Generated By:** (b) (4)**Form:** UNPLANNED 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):** 06-Apr-2021 15:36[Back to Form](#)**I. Assessments**

Date	Location	User	Value	Reason
Jan-19-2021 13:55:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-19-2021 13:55:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Jan-19-2021 13:55:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: CONTACT OUTCOME	Initial Entry

Header Text: c4591001**Visit:** Unplanned 1 - Unscheduled Visit on
Jan/15/2021**Form Version:** 22-Apr-2020 21:04**Site No:** 1039**Subject No:** 10391337**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):** 06-Apr-2021 15:36[Back to Form](#)**1. Contact Type:**

Date	Location	User	Value	Reason
Jan-19-2021 13:55:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Jan-19-2021 13:55:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: YES Date of Contact: Jan/15/2021 Contact Outcome: VISIT NOT REQUIRED, IN VESTIGATOR DECISION	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 20-Feb-2021 02:26

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Mar-10-2021 10:52:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/9/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-10-2021 10:52:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-10-2021 10:52:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1039

Subject No: 10391337

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

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

Subject Initials: ---

Generated Time (GMT): 06-Apr-2021 15:36

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1. Subject Status

Date	Location	User	Value	Reason
Mar-10-2021 10:52:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Jan-12-2021 13:22:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Jan-12-2021 13:21:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Mar-10-2021 10:52:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Mar/9/2021	Initial Entry
Jan-12-2021 13:22:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Jan/12/2021	Initial Entry
Jan-12-2021 13:21:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Jan/12/2021	Initial Entry

090177e196b72783\Final\Final On: 06-Apr-2021 19:10 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1039

Subject No: 10391337

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): 06-Apr-2021 15:36

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1. Casebook Signature

Date	Location	User	Value	Reason
Mar-11-2021 12:18:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gretchen Crook (b) (4)	<u>Data Entry:</u> Click Here to Enable	Initial Entry