

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT SELECTION

**Form Version:** 30-Jul-2020 21:29

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Cohort Selection**

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

1.	Select appropriate response - Protocol version	24 JUL 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** MAIN INFORMED CONSENT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/11/2020
----	--------------	--

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[10901140]
2.	Birth Date:	(b) (6)/1976
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Aug/11/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**Form Comments**

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

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

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** DISPOSITION - SCREENING

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation/Death	Aug/11/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**eCRF Audit Trail History**

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Latex Allergy]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Allergy to Dust]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Allergy to Tomatoes]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Allergic Rhinitis]
	Start Date:	UNK/UNK/1980
	Ongoing:	YES

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Asthma]
	Start Date:	UNK/UNK/1980
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Asthmatic Bronchitis]
	Start Date:	UNK/UNK/1985
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Kidney Stones]
	Start Date:	UNK/UNK/1996
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Endometriosis]
	Start Date:	UNK/UNK/2003
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[polycystic ovarian syndrome]
	Start Date:	UNK/UNK/2003
	Ongoing:	YES

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Type II Diabetes]
	Start Date:	Jun/UNK/2020
	Ongoing:	YES
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Eczema]
	Start Date:	UNK/UNK/1985
	Ongoing:	YES
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Meniscus Repair Surgery due to meniscus tear]
	Start Date:	UNK/UNK/2016
	Ongoing:	NO End Date: UNK/UNK/2016
1.m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[ACL surgery]
	Start Date:	UNK/UNK/2003
	Ongoing:	NO End Date: UNK/UNK/2003

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

1 n	Line/MH Number:	[14]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[torn ACL]
	Start Date:	UNK/UNK/2003
	Ongoing:	NO End Date: UNK/UNK/2003

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - BASELINE

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Aug/11/2020
2.	Weight:	[124.0]
3.	Unit:	kg
4.	Height:	[165.0]
5.	Unit:	cm
6.	Body Mass Index:	[45.5]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[98.4]
	Unit:	F
	Temperature Location:	ORAL CAVITY

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**eCRF Audit Trail History**

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/11/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** RANDOMIZATION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Aug/11/2020
2.	Randomization Number:	[46471]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/11/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP3GCY]
5.b	Sample ID	[BP3GCX]
5.c	Sample ID	[BP3GCW]
5.d	Sample ID	[BPLG1R]
5.e	Sample ID	[BPLG1S]

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/11/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP3GCN]
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090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** VACCINATION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**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:	Aug/11/2020 16:20
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** REACTOGENICITY DIARY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[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:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Aug/31/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 30-Jul-2020 21:30

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

[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

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 30-Jul-2020 21:30

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERD MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERD 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:	RIGHT
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

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - TEMP

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Aug/31/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[98.3]
	Unit:	F
	Temperature Location:	ORAL CAVITY

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/31/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/31/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BN67X3]
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090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** VACCINATION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**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:	Aug/31/2020 16:10
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)



**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Oct/2/2020
2.	Erroneous Visit	

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

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

**Form Version:** 30-Jul-2020 21:30

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

[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

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

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

**Form Version:** 30-Jul-2020 21:30

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	RIGHT
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

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP8FX5]
5.b	Sample ID	[BLB88J]
5.c	Sample ID	[BLB88K]

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit      **Form:** DATE OF VISIT - ILLNESS ONSET

**Form Version:** 22-Apr-2020 21:03      **Form Status:** Not Started

**Site No:** 1090      **Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 10:31

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit      **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

**Form Version:** 20-Feb-2021 02:17

**Form Status:** Not Started

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**Signs and Symptoms**

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

**Symptoms**

4.	Symptoms:	
	Was symptom present?	

**Symptoms - Other**

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

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**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	[ ]
----	-----------	-----

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**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	[ ]
----	-----------	-----

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit      **Form:** HEALTH CARE UTILIZATION

**Form Version:** 20-Feb-2021 02:19      **Form Status:** Not Started

**Site No:** 1090      **Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 10:31

**Health Care Utilization**

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

**Health Care Utilization Other**

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

**Health Care Utilization**

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

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit      **Form:** ILLNESS DETAILS

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Not Started

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**Illness Details**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA - New  
Unscheduled Visit

**Form:** DATE OF VISIT - ILLNESS CONVALESCENT

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Not Started

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA - New  
Unscheduled Visit

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**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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090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** UNPLANNED VISIT

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Not Started

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**Unplanned Assessments**

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

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation/Death :	Oct/2/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**Disposition - Follow-Up**

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



**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New      **Form:** DATE OF VISIT - REPEAT SWAB  
Unscheduled Visit

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

**Site No:** 1090      **Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 10:31

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

3.	COVID-19 Repeat Swab:	
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090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB  
Unscheduled Visit

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**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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**Header Text:** c4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	acute appendicitis with perforation	Feb/4/2021 UNK:UNK	NO End Date Time:  Feb/11/2021 UNK:UNK	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	localized peritonitis	Feb/4/2021 UNK:UNK	NO End Date Time:  Feb/11/2021 UNK:UNK	<a href="#">Repeating Pages</a>
3.	ADVERSE EVENT	3	pelvic abscess	Feb/4/2021 UNK:UNK	NO End Date Time:  Feb/11/2021 UNK:UNK	<a href="#">Repeating Pages</a>

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Not Complete

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[acute appendicitis with perforation]
4.	Start Date Time:	Feb/4/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/11/2021 UNK:UNK
6.	Toxicity Grade:	4
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES  Is this serious event associated with congenital anomaly or birth defect? NO  Did this serious event result in death? NO  Did this serious event require or prolong hospitalization? YES  Did this serious event result in persistent or significant disability/incapacity? NO  Is this serious event life threatening? YES  Other medically important serious event 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

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Not Complete

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unknown]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
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	[2021162151]

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**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1090**Subject No:** 10901140**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete**Site Name:** (1090) Wake Research Associates, LLC**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:31

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[localized peritonitis]
4.	Start Date Time:	Feb/4/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/11/2021 UNK:UNK
6.	Toxicity Grade:	4
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES  Is this serious event associated with congenital anomaly or birth defect? NO  Did this serious event result in death? NO  Did this serious event require or prolong hospitalization? YES  Did this serious event result in persistent or significant disability/incapacity? NO  Is this serious event life threatening? YES  Other medically important serious event 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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [appendicitis]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
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	[2021162151]

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**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1090**Subject No:** 10901140**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete**Site Name:** (1090) Wake Research Associates, LLC**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:31

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[pelvic abscess]
4.	Start Date Time:	Feb/4/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/11/2021 UNK:UNK
6.	Toxicity Grade:	4
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES  Is this serious event associated with congenital anomaly or birth defect? NO  Did this serious event result in death? NO  Did this serious event require or prolong hospitalization? YES  Did this serious event result in persistent or significant disability/incapacity? NO  Is this serious event life threatening? YES  Other medically important serious event 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



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [appendicitis]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
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	[2021162151]

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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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	[ ]

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - NON STUDY  
VACCINATIONS

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

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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:	//

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**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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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?	

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**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[Back to Form](#)

**Radiation Treatment**

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

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

#	Transfusion Type	Date of Transfusion	Form Instance
1.			<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[Back to Form](#)

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VITAL SIGNS - TEMP

**Form Version:** 20-Feb-2021 02:16

**Form Status:** Not Started

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**Vital Signs**

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

**Vital Signs Details**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Version:** 20-Feb-2021 02:14

**Form Status:** Not Started

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**Lab Urinalysis**

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

**Lab Result**

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

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Not Started

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**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?	

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 1

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**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:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** FURTHER VACCINATION CONFIRMATION

**Form Version:** 10-Dec-2020 02:25

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	---

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** TREATMENT UNBLINDED

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Jan/25/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Not Started

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**Withdrawal Of Consent**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** DEATH DETAILS CODED

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**Death Details**

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

**Cause of Death**

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

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/27/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:31

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** INFORMED CONSENT - FURTHER VACCINATION

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Informed Consent - Further Vaccination**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/27/2021
----	--------------	--



**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

**Form Version:** 10-Dec-2020 02:30

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**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
----	--	----------------

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION

**Form Version:** 10-Dec-2020 02:31

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Disposition - Screening for Further Vaccination**

1.	Date of Completion/Discontinuation/Death :	Jan/27/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jan/27/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/27/2021
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	[BMN9F6]
5.b	Sample ID	[BMN9F5]
5.c	Sample ID	[BP8G46]

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/27/2021
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	[BP8G3L]
-----	-----------	----------

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** VACCINATION

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**eCRF Audit Trail History**

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/27/2021 13:32
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/18/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Feb/18/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)



**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/18/2021
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	[BV0F6P]
-----	-----------	----------

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** VACCINATION

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**eCRF Audit Trail History**

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/18/2021 14:34
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V103\_MONTH1

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V104\_MONTH6

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V104\_MONTH6

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V105\_MONTH18

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V105\_MONTH18

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**Contact Outcome**

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



**Header Text:** c4591001

**Visit:** FURTHER\_VACCINATION\_EOT -  
Unscheduled

**Form:** DISPOSITION - TREATMENT

**Form Version:** 20-Feb-2021 02:26

**Form Status:** Not Started

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**Disposition - Treatment**

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

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Subject Status**

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

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

[Audit Trail](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Lisa Cohen	Approved	Mar-12-2021 08:43:25 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

**Affidavit:**

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

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

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

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-12-2020 14:55:26 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER  
VACCINATION - Comments

**Form Version:** 10-Dec-2020 02:30

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-27-2021 14:21:19 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

[Back to Form](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Lisa Cohen	Approved	Mar-12-2021 08:43:25 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

**Affidavit:**

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

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

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

(b) (6)	N/A	Mar-11-2021 15:44:57 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Lisa Cohen	Approved	Mar-11-2021 09:04:18 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

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

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

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

(b) (6)	N/A	Mar-11-2021 08:54:38 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001**Visit:** Investigator Signature - Unscheduled**Form:** CASEBOOK SIGNATURE FORM - Signature History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Signed, Verified**Site No:** 1090**Site Name:** (1090) Wake Research Associates, LLC**Subject No:** 10901140**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:31

Matthew Hong	Approved	Mar-10-2021 16:54:33 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
<p><b>Affidavit:</b> By my dated signature below, I, MatthewHong, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.</p> <p>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.</p> <p>To this I do attest by supplying my user name and password and clicking the button marked Submit below.</p>				
(b) (6)	N/A	Mar-10-2021 14:34:39 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
<p><b>Affidavit:</b> N/A</p>				
Lisa Cohen	Approved	Mar-10-2021 09:01:09 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
<p><b>Affidavit:</b> By my dated signature below, I, LisaCohen, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.</p> <p>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.</p> <p>To this I do attest by supplying my user name and password and clicking the button marked Submit below.</p>				
(b) (6)	N/A	Mar-10-2021 08:17:33 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
<p><b>Affidavit:</b> N/A</p>				
Lisa Cohen	Approved	Mar-10-2021 07:55:13 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed



**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**Affidavit:**

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

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

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

(b) (6)	N/A	Mar-09-2021 13:08:32 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Matthew Hong	Approved	Feb-19-2021 15:38:59 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

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

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

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

(b) (6)	N/A	Feb-19-2021 13:42:39 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Matthew Hong	Approved	Feb-19-2021 09:24:28 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**Affidavit:**

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

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

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

(b) (6)	N/A	Feb-19-2021 03:23:10 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Matthew Hong	Approved	Feb-18-2021 17:18:43 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

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

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

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

(b) (6)	N/A	Feb-18-2021 16:22:47 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Matthew Hong	Approved	Feb-18-2021 14:00:50 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**Affidavit:**

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

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

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

(b) (6)	N/A	Feb-18-2021 13:15:53 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Matthew Hong	Approved	Feb-01-2021 12:05:19 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

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

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

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

(b) (6)	N/A	Feb-01-2021 10:03:51 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Matthew Hong	Approved	Jan-29-2021 12:27:48 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001**Visit:** Investigator Signature - Unscheduled**Form:** CASEBOOK SIGNATURE FORM - Signature History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Signed, Verified**Site No:** 1090**Site Name:** (1090) Wake Research Associates, LLC**Subject No:** 10901140**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:31**Affidavit:**

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

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

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

(b) (6)	N/A	Jan-29-2021 12:06:55 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
<b>Affidavit:</b> N/A				
Matthew Hong	Approved	Jan-27-2021 14:35:47 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
<b>Affidavit:</b> By my dated signature below, I, MatthewHong, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.  Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.  To this I do attest by supplying my user name and password and clicking the button marked Submit below.				
(b) (6)	N/A	Jan-27-2021 14:20:15 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
<b>Affidavit:</b> N/A				
Wayne Harper	Approved	Oct-08-2020 15:45:00 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**Affidavit:**

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

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

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

(b) (6)	N/A	Oct-02-2020 16:47:47 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Wayne Harper	Approved	Sep-11-2020 13:47:06 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, WayneHarper, 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.

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** COHORT\_SELECTION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[Back to Form](#)

*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Aug-12-2020 14:54:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 14:54:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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**I. Consent Was:**

Date	Location	User	Value	Reason
Aug-12-2020 14:54:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Aug/11/2020	Initial Entry

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1090

Subject No: 10901140

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1090) Wake Research Associates, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

[Back to Form](#)

**1. Subject ID**

Date	Location	User	Value	Reason
Aug-12-2020 14:54:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10901140	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Aug-12-2020 14:53:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6) /1976	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Aug-12-2020 14:54:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Aug-12-2020 14:54:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 14:54:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Aug-12-2020 14:55:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/11/2020	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1090

Subject No: 10901140

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1090) Wake Research Associates, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

[Back to Form](#)

**1. Date of Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Aug-12-2020 14:56:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/11/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Aug-12-2020 14:56:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Aug-12-2020 14:56:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1090

Subject No: 10901140

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1090) Wake Research Associates, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

[Back to Form](#)

*I.a*

Date	Location	User	Value	Reason
Aug-12-2020 14:57:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 1 <b>Medical History</b> Latex Allergy <b>Term:</b> y <b>Start Date:</b> UNK/UNK/1990 <b>Ongoing:</b> YES	Initial Entry

*I.a Line/MH Number:*

Date	Location	User	Value	Reason
Aug-12-2020 14:57:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 14:57:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Latex Allergy	Initial Entry

*I.a Start Date:*

Date	Location	User	Value	Reason
Aug-12-2020 14:57:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1990	Initial Entry

*I.a Ongoing:*

Date	Location	User	Value	Reason
Aug-12-2020 14:57:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1090

Subject No: 10901140

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1090) Wake Research Associates, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

**I.b**

Date	Location	User	Value	Reason
Aug-12-2020 14:57:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 2 <b>Medical History Term:</b> Allergy to Dust <b>Start Date:</b> UNK/UNK/1990 <b>Ongoing:</b> YES	Initial Entry

**I.b Line/MH Number:**

Date	Location	User	Value	Reason
Aug-12-2020 14:57:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 14:57:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Allergy to Dust	Initial Entry

**I.b Start Date:**

Date	Location	User	Value	Reason
Aug-12-2020 14:57:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1990	Initial Entry

**I.b Ongoing:**

Date	Location	User	Value	Reason
Aug-12-2020 14:57:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.c**

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1090

Subject No: 10901140

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1090) Wake Research Associates, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

Date	Location	User	Value	Reason
Aug-12-2020 14:58:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 3 <b>Medical History</b> Allergy to Tomatoes <b>Term:</b> matoes <b>Start Date:</b> UNK/UNK/1990 <b>Ongoing:</b> YES	Initial Entry

*I.c Line/MH Number:*

Date	Location	User	Value	Reason
Aug-12-2020 14:58:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 14:58:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Allergy to Tomatoes	Initial Entry

*I.c Start Date:*

Date	Location	User	Value	Reason
Aug-12-2020 14:58:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1990	Initial Entry

*I.c Ongoing:*

Date	Location	User	Value	Reason
Aug-12-2020 14:58:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

*I.d*

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: 1090

Subject No: 10901140

Generated By: (b) (4)

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Aug-12-2020 15:02:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 4 <b>Medical History Term:</b> Allergic Rhinitis <b>Start Date:</b> UNK/UNK/1980 <b>Ongoing:</b> YES	Initial Entry
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***1.d Line/MH Number:***

Date	Location	User	Value	Reason
Aug-12-2020 15:02:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 15:02:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Allergic Rhinitis	Initial Entry

***1.d Start Date:***

Date	Location	User	Value	Reason
Aug-12-2020 15:02:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1980	Initial Entry

***1.d Ongoing:***

Date	Location	User	Value	Reason
Aug-12-2020 15:02:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***1.e***

Date	Location	User	Value	Reason
Aug-12-2020 15:02:37	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Initial Entry

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Site No: 1090

Subject No: 10901140

Generated By: (b) (4)

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Subject Initials: ---

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(UTC-05:00) Eastern Time (US & Canada)		(autocalc)	Line/MH Number: 5 Medical History: Asthma Term: Start Date: UNK/UNK/1980 Ongoing: YES	
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*I.e Line/MH Number:*

Date	Location	User	Value	Reason
Aug-12-2020 15:02:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 15:02:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Asthma	Initial Entry

*I.e Start Date:*

Date	Location	User	Value	Reason
Aug-12-2020 15:02:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: UNK/UNK/1980	Initial Entry

*I.e Ongoing:*

Date	Location	User	Value	Reason
Aug-12-2020 15:02:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES	Initial Entry

*I.f*

Date	Location	User	Value	Reason
Aug-12-2020 15:03:06 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 6	Initial Entry

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Subject No: 10901140

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Time (US & Canada)			er: Medical History Term: Start Date: Ongoing:	Asthmatic Bro nchitis UNK/UNK/19 85 YES
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**I.f Line/MH Number:**

Date	Location	User	Value	Reason
Aug-12-2020 15:03:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 6	Initial Entry

**I.f Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Aug-12-2020 15:03:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Asthmatic Bronchitis	Initial Entry

**I.f Start Date:**

Date	Location	User	Value	Reason
Aug-12-2020 15:03:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1985	Initial Entry

**I.f Ongoing:**

Date	Location	User	Value	Reason
Aug-12-2020 15:03:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.g**

Date	Location	User	Value	Reason
Aug-12-2020 15:03:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Numbe r: 7	Initial Entry

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Subject No: 10901140

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			<b>Medical History Term:</b> <b>Start Date:</b> <b>Ongoing:</b>	Kidney Stones UNK/UNK/1996 YES
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**I.g Line/MH Number:**

Date	Location	User	Value	Reason
Aug-12-2020 15:03:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 15:03:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Kidney Stones	Initial Entry

**I.g Start Date:**

Date	Location	User	Value	Reason
Aug-12-2020 15:03:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1996	Initial Entry

**I.g Ongoing:**

Date	Location	User	Value	Reason
Aug-12-2020 15:03:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.h**

Date	Location	User	Value	Reason
Aug-12-2020 15:04:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 8	Initial Entry

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			<b>Medical History Term:</b> <b>Start Date:</b> <b>Ongoing:</b>	Endometriosis UNK/UNK/2003 YES
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**1.h Line/MH Number:**

Date	Location	User	Value	Reason
Aug-12-2020 15:04:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 8	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 15:04:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Endometriosis	Initial Entry

**1.h Start Date:**

Date	Location	User	Value	Reason
Aug-12-2020 15:04:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2003	Initial Entry

**1.h Ongoing:**

Date	Location	User	Value	Reason
Aug-12-2020 15:04:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.i**

Date	Location	User	Value	Reason
Aug-15-2020 12:36:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Line/MH Number: 9	this is the medical term

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**Subject No:** 10901140

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			<b>Medical History Term:</b> polycystic ovarian syndrome <b>Start Date:</b> UNK/UNK/2003 <b>Ongoing:</b> YES	
Aug-12-2020 15:05:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 9 <b>Medical History Term:</b> Polycystic Ovarian Syndrome <b>Start Date:</b> UNK/UNK/2003 <b>Ongoing:</b> YES	Initial Entry

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**1.i Line/MH Number:**

Date	Location	User	Value	Reason
Aug-12-2020 15:05:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 9	Initial Entry

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

Date	Location	User	Value	Reason
Aug-15-2020 13:32:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 2: Closed	Discrepancy has been closed.
Aug-15-2020 12:36:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	this is the medical term
Aug-15-2020 12:36:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> polycystic ovarian syndrome	this is the medical term
Aug-14-2020 07:25:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Closed by DM: PM_Related query has been issued
Aug-13-2020 00:28:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 2: Opened	Spacing: Verbatim Term contains leading, trailing or more than one consecutive space.
Aug-12-2020 15:05:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Extra blank spaces are present between words in the Disease/Syndrome

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				Term which may impact coding. Please review and remove any extra spaces.
Aug-12-2020 15:05:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entr</b> <b>y:</b> Polycystic Ovarian S yndrome	Initial Entry

Header Text: c4591001

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Subject No: 10901140

Generated By: (b) (4)

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**1.i Start Date:**

Date	Location	User	Value	Reason
Aug-12-2020 15:05:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2003	Initial Entry

**1.i Ongoing:**

Date	Location	User	Value	Reason
Aug-12-2020 15:05:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.j**

Date	Location	User	Value	Reason
Aug-12-2020 15:06:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number</b> 10 : <b>Medical History T</b> Type II Diab <b>erm:</b> etes <b>Start Date:</b> Jun/UNK/20 20 <b>Ongoing:</b> YES	Initial Entry

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Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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**1.j Line/MH Number:**

Date	Location	User	Value	Reason
Aug-12-2020 15:06:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10	Initial Entry

**1.j Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Aug-17-2020 08:58:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Patricia Banchero (b) (4)	Query 1: Closed	Response satisfies query
Aug-15-2020 12:34:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	stable disease
Aug-14-2020 08:50:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Patricia Banchero (b) (4)	Query 1: Opened	Per IC #3, medical history condition must be stable at least 6 weeks before enrollment. Please confirm if any significant change in therapy or hospitalization for worsening disease occured during the 6 weeks prior to enrollment.
Aug-12-2020 15:06:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Type II Diabetes	Initial Entry

**1.j Start Date:**

Date	Location	User	Value	Reason
Aug-12-2020 15:06:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Jun/UNK/2020	Initial Entry

**1.j Ongoing:**

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**Site Name:** (1090) Wake Research Associates, LLC

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Date	Location	User	Value	Reason
Aug-12-2020 15:06:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

*l.k*

Date	Location	User	Value	Reason
Aug-12-2020 15:08:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 11 <b>r:</b> <b>Medical History:</b> Eczema <b>Term:</b> <b>Start Date:</b> UNK/UNK/1 985 <b>Ongoing:</b> YES	Initial Entry

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Date	Location	User	Value	Reason
Aug-12-2020 15:08:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 15:08:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Eczema	Initial Entry

***1.k Start Date:***

Date	Location	User	Value	Reason
Aug-12-2020 15:08:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1985	Initial Entry

***1.k Ongoing:***

Date	Location	User	Value	Reason
Aug-12-2020 15:08:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***1.l***

Date	Location	User	Value	Reason
Aug-12-2020 15:09:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 12 <b>Number:</b> <b>Medical H</b> Meniscus Repair Sur <b>istory Ter</b> gery due to meniscus <b>m:</b> tear <b>Start Date</b> UNK/UNK/2016 :	Initial Entry

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			Ongoing: NO End Date:  UNK/UNK/2016	
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**1.1 Line/MH Number:**

Date	Location	User	Value	Reason
Aug-12-2020 15:09:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 12	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 15:09:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Meniscus Repair Surgery due to meniscus tear	Initial Entry

**1.1 Start Date:**

Date	Location	User	Value	Reason
Aug-12-2020 15:09:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2016	Initial Entry

**1.1 Ongoing:**

Date	Location	User	Value	Reason
Aug-12-2020 15:09:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2016	Initial Entry

**1.m**

Date	Location	User	Value	Reason
Aug-15-2020 12:36:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Line/MH Number: er:	New Information

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			<b>Medical History Term:</b> ACL surgery <b>Start Date:</b> UNK/UNK/2003 <b>Ongoing:</b> NO End Date: UNK/UNK/2003	
Aug-12-2020 15:10:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 13 <b>Medical History Term:</b> ACL surgery due to torn ACL <b>Start Date:</b> UNK/UNK/2003 <b>Ongoing:</b> NO End Date: UNK/UNK/2003	Initial Entry

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Site No: 1090

Subject No: 10901140

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1090) Wake Research Associates, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

***1.m Line/MH Number:***

Date	Location	User	Value	Reason
Aug-12-2020 15:10:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 13	Initial Entry

***1.m Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Aug-15-2020 13:33:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Aug-15-2020 12:36:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Aug-15-2020 12:36:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> ACL surgery	New Information
Aug-13-2020 04:30:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Multiple concepts in the term ACL SURGERY DUE TO TORN ACL. Split the term into ACL SURGERY and TORN ACL and submit separately. Thank you.
Aug-12-2020 15:10:41	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ACL surgery	Initial Entry

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1090

Subject No: 10901140

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1090) Wake Research Associates, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

(UTC-05:00) Eastern Time (US & Canada)			due to torn A CL	
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***I.m Start Date:***

Date	Location	User	Value	Reason
Aug-12-2020 15:10:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2003	Initial Entry

***I.m Ongoing:***

Date	Location	User	Value	Reason
Aug-12-2020 15:10:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2003	Initial Entry

***I.n***

Date	Location	User	Value	Reason
Aug-15-2020 12:37:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 14 <b>Medical History Term:</b> torn ACL <b>Start Date:</b> UNK/UNK/2003 <b>Ongoing:</b> NO End Date:  UNK/UNK/2003	Initial Entry

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1090

Subject No: 10901140

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1090) Wake Research Associates, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

***I.n Line/MH Number:***

Date	Location	User	Value	Reason
Aug-15-2020 12:37:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 14	Initial Entry

***I.n Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Aug-15-2020 12:37:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> torn ACL	Initial Entry

***I.n Start Date:***

Date	Location	User	Value	Reason
Aug-15-2020 12:37:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2003	Initial Entry

***I.n Ongoing:***

Date	Location	User	Value	Reason
Aug-15-2020 12:37:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2003	Initial Entry

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:28

Site No: 1090

Subject No: 10901140

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1090) Wake Research Associates, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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**1. Date:**

Date	Location	User	Value	Reason
Aug-12-2020 15:17:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/11/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Aug-12-2020 15:17:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> 124.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Aug-12-2020 15:17:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Aug-12-2020 15:17:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> 165.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Aug-12-2020 15:17:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> cm	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
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090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:28

Site No: 1090

Subject No: 10901140

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1090) Wake Research Associates, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

Aug-12-2020 15:17:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 45.5	Initial Entry
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7.a

Date	Location	User	Value	Reason
Aug-12-2020 15:17:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier</b> 1 :: <b>Temperature:</b> 98.4 <b>Temperature Unit</b> F : <b>Temperature Loc</b> ORAL CAV <b>ation::</b> ITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-12-2020 15:17:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-12-2020 15:17:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> 98.4	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-12-2020 15:17:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-12-2020 15:17:23	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

(UTC-05:00) Eastern  
Time (US & Canada)

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

ORAL CAVITY

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1090

Site Name: (1090) Wake Research Associates, LLC

Subject No: 10901140

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Aug-12-2020 15:17:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Aug-12-2020 15:17:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Aug-12-2020 15:17:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Aug/11/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Aug-12-2020 15:17:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Aug-12-2020 15:17:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1090

Site Name: (1090) Wake Research Associates, LLC

Subject No: 10901140

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

Aug-12-2020 15:17:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> NEGATIVE <b>Not Done::</b>	Initial Entry
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**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Aug-12-2020 15:17:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Aug-12-2020 15:17:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Aug-12-2020 15:17:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** RANDOMIZATION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Aug-12-2020 15:18:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/11/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Aug-12-2020 15:18:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 46471	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1090

Site Name: (1090) Wake Research Associates, LLC

Subject No: 10901140

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-12-2020 15:18:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-12-2020 15:18:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-13-2020 08:33:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Aug-13-2020 01:21:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-12-2020 15:19:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-12-2020 15:19:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-12-2020 15:19:02 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Transcription Error

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY  
- eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1090**Site Name:** (1090) Wake Research Associates, LLC**Subject No:** 10901140**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:31

Time (US & Canada)			Date of Collection: Aug/11/2020	
Aug-12-2020 15:18:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Aug-12-2020 15:18:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-13-2020 08:33:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BP3GCY</b>	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-13-2020 08:33:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP3GCY	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Aug-13-2020 08:33:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BP3GCX</b>	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1090

Site Name: (1090) Wake Research Associates, LLC

Subject No: 10901140

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

5.b Sample ID

Date	Location	User	Value	Reason
Aug-13-2020 08:33:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP3GCX	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-13-2020 08:34:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BP3GCW	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-13-2020 08:34:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP3GCW	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-13-2020 08:34:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPLG1R	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-13-2020 08:34:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPLG1R	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-13-2020 08:34:57 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPLG1S	Initial Entry

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

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

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

Time (US & Canada)	(b) (4), (b) (6)
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**5.e Sample ID**

Date	Location	User	Value	Reason
Aug-13-2020 08:34:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPLG1S	Initial Entry



**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1090**Site Name:** (1090) Wake Research Associates, LLC**Subject No:** 10901140**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:31[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-12-2020 15:19:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-12-2020 15:19:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-13-2020 08:35:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-13-2020 01:21:02 (UTC-05:00) Eastern 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.
Aug-12-2020 15:19:32 (UTC-05:00) Eastern 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.
Aug-12-2020 15:19:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES Date of Collection:	Initial Entry

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

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

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

			Aug/11/2020	
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**5.a**

Date	Location	User	Value	Reason
Aug-13-2020 08:35:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP3GCN	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-13-2020 08:35:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP3GCN	Initial Entry

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1090

Subject No: 10901140

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1090) Wake Research Associates, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Aug-12-2020 15:20:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Aug-12-2020 15:20:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Aug-12-2020 15:20:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Aug-12-2020 15:20:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Aug/11/2020 16:20	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-12-2020 15:20:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
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090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1090

Subject No: 10901140

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1090) Wake Research Associates, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

Aug-12-2020 15:20:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RIGHT	Initial Entry
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**7. Route:**

Date	Location	User	Value	Reason
Aug-12-2020 15:20:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Aug-12-2020 15:20:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 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
Aug-12-2020 15:20:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Aug-12-2020 15:20:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

[Back to Form](#)

*I. Date of Visit*

Date	Location	User	Value	Reason
Sep-01-2020 08:34:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/31/2020	Initial Entry

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 30-Jul-2020 21:30**Site No:** 1090**Subject No:** 10901140**Generated By:** (b) (4)**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1090) Wake Research Associates, LLC**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:31[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
Sep-01-2020 08:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-01-2020 08:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FE VE R  <b>Were fever or systemic s N ymptoms present on the O last day the Subject Diar y was completed?:</b>	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Sep-01-2020 08:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Sep-01-2020 08:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Sep-01-2020 08:35:15 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FA	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1090

Site Name: (1090) Wake Research Associates, LLC

Subject No: 10901140

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

Time (US & Canada)		(b) (4), (b) (6)	TI GU E	Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO
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2.b Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 08:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 08:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-01-2020 08:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)



Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1090

Site Name: (1090) Wake Research Associates, LLC

Subject No: 10901140

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

2.c Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 08:35:15 (UTC-05:00) Eastern 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
Sep-01-2020 08:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-01-2020 08:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: CH IL LS  Were fever or systemic s N ymptoms present on the O last day the Subject Diar y was completed?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 08:35:15 (UTC-05:00) Eastern 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
Sep-01-2020 08:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1090

Site Name: (1090) Wake Research Associates, LLC

Subject No: 10901140

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

2.e

Date	Location	User	Value	Reason
Sep-01-2020 08:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> VO MIT ING  <b>Were fever or systemic symptoms present on t he last day the Subject Diary was completed?:</b> NO	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 08:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Sep-01-2020 08:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-01-2020 08:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DIA RR HE A  <b>Were fever or systemic symptoms present on th e last day the Subject D iary was completed?:</b> NO	Initial Entry

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1090

Site Name: (1090) Wake Research Associates, LLC

Subject No: 10901140

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

2.f Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 08:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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
Sep-01-2020 08:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-01-2020 08:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: NEW O R WORS ENED M USCLE PAIN  Were fever or syst NO emic symptoms pr esent on the last da y the Subject Diar y was completed?:	Initial Entry

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1090

Site Name: (1090) Wake Research Associates, LLC

Subject No: 10901140

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

2.g Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 08:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENERED MUS CLE 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
Sep-01-2020 08:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Sep-01-2020 08:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW O R WOR SENERED JOINT P AIN  <b>Were fever or syste NO mic symptoms pres ent on the last day the Subject Diary was completed?:</b>	Initial Entry

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1090

Site Name: (1090) Wake Research Associates, LLC

Subject No: 10901140

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

2.h Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 08:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR WORSENER JOIN T 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
Sep-01-2020 08:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-01-2020 08:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-01-2020 08:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RIGHT	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-01-2020 08:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <b>Injection Site Reaction:</b> RE : DN ES S  <b>Were injection site reac</b> NO <b>tions present on the last</b> <b>day the Subject Diary w</b> <b>as completed?:</b>	Initial Entry

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1090

Site Name: (1090) Wake Research Associates, LLC

Subject No: 10901140

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-01-2020 08:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 08:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-01-2020 08:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction SW :: ELL ING  Were injection site reac NO tions present on the las t day the Subject Diary was completed?:	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-01-2020 08:35:15 (UTC-05:00) Eastern 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
Sep-01-2020 08:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1090

Site Name: (1090) Wake Research Associates, LLC

Subject No: 10901140

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

5.c

Date	Location	User	Value	Reason
Sep-01-2020 08:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> PAIN AT INJECTION SITE  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-01-2020 08:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Sep-01-2020 08:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 21-Aug-2020 02:51

Site No: 1090

Subject No: 10901140

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1090) Wake Research Associates, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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**1. Date:**

Date	Location	User	Value	Reason
Sep-01-2020 08:35:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/31/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-01-2020 08:35:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Record Identifier: 1 r:: Temperature: 98.3 Temperature Unit: F Temperature Location: ORAL CAVITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-01-2020 08:35:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Sep-01-2020 08:35:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 98.3	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Sep-01-2020 08:35:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Sep-01-2020 08:35:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1090

Site Name: (1090) Wake Research Associates, LLC

Subject No: 10901140

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-01-2020 08:35:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Sep-01-2020 08:35:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Sep-01-2020 08:35:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/31/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Sep-01-2020 08:35:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Sep-01-2020 08:35:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
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090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1090

Site Name: (1090) Wake Research Associates, LLC

Subject No: 10901140

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

Sep-01-2020 08:35:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 113 <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> NEGATIVE <b>Not Done::</b>	Initial Entry
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**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Sep-01-2020 08:35:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Sep-01-2020 08:35:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX1 13	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Sep-01-2020 08:35:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1090**Site Name:** (1090) Wake Research Associates, LLC**Subject No:** 10901140**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:31[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-31-2020 16:40:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-31-2020 16:40:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-31-2020 16:40:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-31-2020 16:40:31 (UTC-05:00) Eastern 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.
Aug-31-2020 16:40:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/31/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-31-2020 16:40:39 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

Time (US & Canada)	(b) (4), (b) (6)	<b>Sample ID:</b> BN67X3
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**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-31-2020 16:40:39 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BN67X3	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1090

Subject No: 10901140

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1090) Wake Research Associates, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Sep-01-2020 08:36:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-01-2020 08:36:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-01-2020 08:36:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Sep-01-2020 08:36:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/31/2020 16:10	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-01-2020 08:36:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
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Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

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Subject No: 10901140

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1090) Wake Research Associates, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

Sep-01-2020 08:36:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RIGHT	Initial Entry
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**7. Route:**

Date	Location	User	Value	Reason
Sep-01-2020 08:36:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Sep-01-2020 08:36:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 08:36:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

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**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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*I. Date of Visit*

Date	Location	User	Value	Reason
Oct-05-2020 08:45:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/2/2020	Initial Entry



**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

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

**Form Version:** 30-Jul-2020 21:30

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

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

Date	Location	User	Value	Reason
Oct-05-2020 08:48:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Oct-05-2020 08:48:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FEVER  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Oct-05-2020 08:48:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Oct-05-2020 08:48:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Oct-05-2020 08:48:48 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FA	Initial Entry

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1090

Site Name: (1090) Wake Research Associates, LLC

Subject No: 10901140

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

Time (US & Canada)	(b) (4), (b) (6)	TI GU E Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	NO
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2.b Symptom:

Date	Location	User	Value	Reason
Oct-05-2020 08:48:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<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
Oct-05-2020 08:48:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Oct-05-2020 08:48:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Symptom::</u> HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

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Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1090

Site Name: (1090) Wake Research Associates, LLC

Subject No: 10901140

Subject Initials: ---

Generated By: (b) (4)

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2.c Symptom:

Date	Location	User	Value	Reason
Oct-05-2020 08:48:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Oct-05-2020 08:48:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Oct-05-2020 08:48:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> CH IL LS <b>Were fever or systemic sy</b> NO <b>mptoms present on the last</b> <b>day the Subject Diary was</b> <b>completed?:</b>	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Oct-05-2020 08:48:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Oct-05-2020 08:48:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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Header Text: c4591001

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Form Status: Data Complete, Locked, Frozen, Verified

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Site Name: (1090) Wake Research Associates, LLC

Subject No: 10901140

Subject Initials: ---

Generated By: (b) (4)

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2.e

Date	Location	User	Value	Reason
Oct-05-2020 08:48:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> VO MIT ING  <b>Were fever or systemic sy NO mptoms present on the la st day the Subject Diary was completed?:</b>	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Oct-05-2020 08:48:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Oct-05-2020 08:48:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Oct-05-2020 08:48:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DIA RR HE A  <b>Were fever or systemic sy NO mptoms present on the las t day the Subject Diary w as completed?:</b>	Initial Entry

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Header Text: c4591001

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1090

Site Name: (1090) Wake Research Associates, LLC

Subject No: 10901140

Subject Initials: ---

Generated By: (b) (4)

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2.f Symptom:

Date	Location	User	Value	Reason
Oct-05-2020 08:48:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Oct-05-2020 08:48:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Oct-05-2020 08:48:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE NED MU SCLE PA IN <b>Were fever or syste</b> NO <b>mic symptoms prese</b> <b>nt on the last day th</b> <b>e Subject Diary was</b> <b>completed?:</b>	Initial Entry

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

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Subject Initials: ---

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2.g Symptom:

Date	Location	User	Value	Reason
Oct-05-2020 08:48:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSE NED JOI NT 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
Oct-05-2020 08:48:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Oct-05-2020 08:48:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE NED JOI NT PAIN  <b>Were fever or system NO ic symptoms present on the last day the S ubject Diary was co mpleted?:</b>	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Oct-05-2020 08:48:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Oct-05-2020 08:48:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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Site Name: (1090) Wake Research Associates, LLC

Subject No: 10901140

Subject Initials: ---

Generated By: (b) (4)

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3. Injection Site Location:

Date	Location	User	Value	Reason
Oct-05-2020 08:48:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Oct-05-2020 08:48:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RIGHT	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-05-2020 08:48:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Injection Site Reaction:: RE DN ESS  Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-05-2020 08:48:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Oct-05-2020 08:48:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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Subject Initials: ---

Generated By: (b) (4)

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5.b

Date	Location	User	Value	Reason
Oct-05-2020 08:48:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> SW ELL ING  <b>Were injection site reacti NO ons present on the last da y the Subject Diary was c ompleted?:</b>	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-05-2020 08:48:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-05-2020 08:48:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-05-2020 08:48:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction PAIN A ::</b> T INJE CTION SITE  <b>Were injection site rea NO ctions present on the l ast day the Subject Di ary was completed?:</b>	Initial Entry

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**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

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

**Form Version:** 30-Jul-2020 21:30

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Oct-05-2020 08:48:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Oct-05-2020 08:48:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY  
- eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1090**Site Name:** (1090) Wake Research Associates, LLC**Subject No:** 10901140**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:31[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-02-2020 16:47:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-02-2020 16:47:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-02-2020 16:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-02-2020 16:47:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-02-2020 16:47:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/2/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-02-2020 16:47:56 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1090

Site Name: (1090) Wake Research Associates, LLC

Subject No: 10901140

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

Time (US & Canada)		(b) (4), (b) (6)	Sample ID: BP8FX5	
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5.a Sample ID

Date	Location	User	Value	Reason
Oct-02-2020 16:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP8FX5	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-02-2020 16:48:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BLB88J	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-02-2020 16:48:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BLB88J	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-02-2020 16:48:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BLB88K	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-02-2020 16:48:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BLB88K	Initial Entry

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Oct-05-2020 08:49:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/2/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-05-2020 08:49:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-05-2020 08:49:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Date	Location	User	Value	Reason
Feb-18-2021 13:15:53 (UTC-05:00) Eastern 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:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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Date	Location	User	Value	Reason
Mar-10-2021 08:20:25 (UTC-05:00) Eastern 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:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

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Date	Location	User	Value	Reason
Mar-10-2021 08:21:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1090

Subject No: 10901140

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Not Complete

Site Name: (1090) Wake Research Associates, LLC

Subject Initials: ---

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**1. Category:**

Date	Location	User	Value	Reason
Feb-18-2021 13:15:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-18-2021 13:15:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Mar-12-2021 13:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Closed	Response satisfies query
Mar-12-2021 07:47:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Answered	faxed already. Subject does not take DM medication
Mar-11-2021 12:48:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Opened	Clinical - please submit a SAE update with the subject's med Hx (including T2DM) and any concomitant medications subject was receiving for

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Not Complete

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

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				T2DM
Mar-11-2021 12:47:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	rewording
Mar-11-2021 12:45:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Opened	Clinical - please submit a SAE update with the subject's med Hx (including T2DM) and all concomitant medications subject was receiving when SAE began
Mar-10-2021 14:37:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Mar-10-2021 09:03:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 3: Closed	Discrepancy has been closed.
Mar-10-2021 08:17:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	per query
Mar-10-2021 08:17:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	per query

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Site No: 1090

Subject No: 10901140

Generated By: (b) (4)

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Form Status: Data Complete, Not Complete

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Mar-10-2021 08:17:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> acute appendicitis with perforation	per query
Mar-10-2021 04:05:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	SAE RECON: AER#2021162151, event term was recorded as 'acute appendicitis with perforation and localized peritonitis with pelvic abscess' for coding and reconciliation. Please consider to split the terms as 3 separate entries to match Safety database.
Mar-09-2021 22:17:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-09-2021 14:37:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4), (b)	Query 3: Opened	Multiple concepts in the term ACUTE APPENDICITIS WITH PERFORATION AND LOCALIZED PERITONITIS WITH PELVIC ABSCCESS. Split the term into ACUTE APPENDICITIS WITH

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**Header Text:** c4591001

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**Form Version:** 22-Apr-2020 21:02

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Not Complete

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**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

				PERFORATION and LOCALIZED PERITONITIS and PELVIC ABSCESS and report as 3 separate entries. Thank you.
Mar-09-2021 13:08:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Mar-09-2021 13:08:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> acute appendicitis with perforation and localized peritonitis with pelvic abscess	New Information
Mar-09-2021 09:34:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical - event term is 'ruptured appendix'; however, SAE report event term updated to 'Acute appendicitis with perforation and located peritonitis, with pelvic abscess'. Please harmonize event reporting, and update where appropriate
Mar-05-2021 21:25:58 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Query closed; will follow for requested surgery date information.

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Subject No: 10901140

Generated By: (b) (4)

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Form Status: Data Complete, Not Complete

Site Name: (1090) Wake Research Associates, LLC

Subject Initials: ---

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(US & Canada)				
Mar-03-2021 17:37:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	surgery was on 08 Feb 2021, we will send in f/u report
Feb-22-2021 09:32:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical - please update SAE report with the specific date that emergency surgery was performed
Feb-18-2021 13:15:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ruptured a ppendix	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-09-2021 13:10:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/4/2021 UNK:UNK	New Information
Mar-09-2021 09:32:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	onset date of 08Feb21 in both locations now
Mar-09-2021 05:25:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2021162151 ,onset date was recorded as 04Feb2021 in Safety database however, recorded as 08Feb2021 on AE CRF. Please confirm correct Onset Date. If safety update is

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Generated By: (b) (4)

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Form Status: Data Complete, Not Complete

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				required, please submit a follow-up SAE form.
Feb-18-2021 13:15:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/8/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-18-2021 13:15:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Feb/11/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-18-2021 13:15:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 4	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
Mar-05-2021 21:25:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Query closed; will follow for requested COVID test information.
Mar-03-2021 17:37:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	we will include that in f/u report
Mar-01-2021 10:55:17 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	Clinical - thank you; please include

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Not Complete

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

Time (US & Canada)		(b) (4), (b) (6)		the COVID test date in the report
Feb-25-2021 17:51:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	it was negative per pt, but we are awaiting medical records to confirm
Feb-22-2021 09:33:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical COVID test status (yes/no) during Hosp was not reported in the SAE. Please submit a follow-up SAE form [#2021162151] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results.
Feb-19-2021 03:23:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-18-2021 13:15:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE ruptured appendix: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-18-2021 13:15:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Is this serious event associated with congenital anomaly or birth defect?  NO Did this serious event result in death?	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1090

Subject No: 10901140

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Not Complete

Site Name: (1090) Wake Research Associates, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

			NO	
			Did this serious event require or prolong hospitalization?	
			YES	
			Did this serious event result in persistent or significant disability/incapacity?	
			NO	
			Is this serious event life threatening?	
			YES	
			Other medically important serious event	
			NO	

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

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

Date	Location	User	Value	Reason
Feb-18-2021 13:15:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Feb-18-2021 13:15:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  unknown	Initial Entry

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Header Text: c4591001

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Site No: 1090

Subject No: 10901140

Generated By: (b) (4)

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Form Status: Data Complete, Not Complete

Site Name: (1090) Wake Research Associates, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-18-2021 13:15:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-09-2021 22:18:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-09-2021 13:08:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Mar-09-2021 13:08:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	New Information
Mar-09-2021 09:33:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical Con Med for event is NO; however SAE update states subject received amoxicillin/clavulanate antibiotic. Please review Con med for event, and update as applicable
Mar-01-2021 10:57:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Query closed; will follow for requested antibiotic usage information.
Feb-25-2021 17:21:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	awaiting medical records for specific antibiotics
Feb-22-2021 09:30:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical - Con Med for SAE is 'NO'; however, SAE report states subject received antibiotics. Please

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Not Complete

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

				review, harmonize reporting, and update where applicable
Feb-18-2021 13:15:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Feb-18-2021 13:15:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-18-2021 13:15:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Feb-18-2021 13:15:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Not Complete

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

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*15. Serious Adverse Event Number: For Pfizer Use Only*

Date	Location	User	Value	Reason
Feb-19-2021 03:23:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2021162151	Initial Entry

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete

**Site Name:** (1090) Wake Research Associates, LLC

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**1. Category:**

Date	Location	User	Value	Reason
Mar-10-2021 08:20:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Mar-10-2021 08:20:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Mar-10-2021 17:10:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Clos ed	Discrepancy has been closed.
Mar-10-2021 14:34:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	Transcription Error
Mar-10-2021 14:34:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> localized peri tonitis	Transcription Error
Mar-10-2021 09:11:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Ope ned	Spacing: Verbatim Term contains leading, trailing or more than one

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1090

Subject No: 10901140

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1090) Wake Research Associates, LLC

Subject Initials: ---

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				consecutive space.
Mar-10-2021 08:20:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> localized peritonitis	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-12-2021 10:44:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-11-2021 09:00:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/4/2021 UNK:UNK	New Information
Mar-11-2021 08:54:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-11-2021 08:54:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/8/2021 UNK:UNK	Transcription Error
Mar-10-2021 14:40:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2021162151 onset date was recorded as 04Feb2021 in Safety database however, recorded as 10Feb2021 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form.
Mar-10-2021 08:22:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/10/2021 UNK:UNK	Transcription Error

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1090

Site Name: (1090) Wake Research Associates, LLC

Subject No: 10901140

Subject Initials: ---

Generated By: (b) (4)

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Mar-10-2021 08:20:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/10/2021 UNK:UNK	Initial Entry
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**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Mar-11-2021 08:59:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Feb/11/2021 UNK:UNK	New Information
Mar-10-2021 08:22:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Feb/10/2021 UNK:UNK	Transcription Error
Mar-10-2021 08:20:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Mar/10/2021 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Mar-10-2021 08:20:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 4	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
Mar-10-2021 14:36:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query

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Visit: Logs - Unscheduled

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Site No: 1090

Subject No: 10901140

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1090) Wake Research Associates, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

Mar-10-2021 08:20:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE localized peritonitis : Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Mar-10-2021 08:20:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<p><b>Data Entry:</b> YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/ incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>YES</p> <p>Other medically important serious event</p> <p>NO</p>	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.**

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Site No: 1090

Site Name: (1090) Wake Research Associates, LLC

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

Date	Location	User	Value	Reason
Mar-10-2021 08:20:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-12-2021 13:27:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-11-2021 15:44:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	per query
Mar-11-2021 15:44:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treat ment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  appendicitis	per query
Mar-11-2021 12:37:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical - other case for event is UNKNOWN; however, the event occurs in the setting of appendicitis. Please review for potential other cause, and update if appropriate
Mar-10-2021 08:20:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treat ment(s), this event is due to:  OTHER	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete

Site No: 1090

Site Name: (1090) Wake Research Associates, LLC

Subject No: 10901140

Subject Initials: ---

Generated By: (b) (4)

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				<i>If Other, specify:</i>
				unk

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Mar-10-2021 08:20:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Mar-10-2021 08:20:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Mar-11-2021 12:36:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	answered
Mar-11-2021 09:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-11-2021 09:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Transcription Error
Mar-11-2021 06:07:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "Was a Non-Drug Treatment given?" is missing. Kindly review and update.

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

Date	Location	User	Value	Reason
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**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

Mar-10-2021 08:20:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry
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**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Mar-10-2021 08:20:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Mar-10-2021 14:36:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2021162151	Initial Entry

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Subject No: 10901140

Generated By: (b) (4)

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**1. Category:**

Date	Location	User	Value	Reason
Mar-10-2021 08:21:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Mar-10-2021 08:21:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Mar-10-2021 08:21:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> pelvic abscess	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Mar-12-2021 10:44:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-11-2021 09:00:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-11-2021 09:00:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/4/2021 UNK:UNK	Transcription Error
Mar-10-2021 14:40:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2021162151 onset date was recorded as

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Form Status: Data Complete

Site Name: (1090) Wake Research Associates, LLC

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				04Feb2021 in Safety database however, recorded as 10Feb2021 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form.
Mar-10-2021 08:21:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/10/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-11-2021 09:01:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Feb/11/2021 UNK:UNK	to match safety dates
Mar-10-2021 08:21:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Feb/10/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-10-2021 08:21:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 4	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).

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Subject No: 10901140

Generated By: (b) (4)

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Site Name: (1090) Wake Research Associates, LLC

Subject Initials: ---

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Date	Location	User	Value	Reason
Mar-10-2021 14:36:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-10-2021 08:21:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE pelvic abscess: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Mar-10-2021 08:21:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> YES Is this serious event associated with congenital anomaly or birth defect?  NO  Did this serious event result in death?  NO  Did this serious event require or prolong hospitalization?  YES  Did this serious event result in persistent or significant disability/incapacity?  NO  Is this serious event life threatening?  YES  Other medically important serious event	Initial Entry

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Site Name: (1090) Wake Research Associates, LLC

Subject No: 10901140

Subject Initials: ---

Generated By: (b) (4)

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			NO	
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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
Mar-10-2021 08:21:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-12-2021 13:29:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-11-2021 15:45:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	per query
Mar-11-2021 15:45:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treat ment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  appendicitis	per query
Mar-11-2021 12:38:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical - other case for event is UNKNOWN; however, the event occurs in the setting of appendicitis. Please review for potential other cause, and update if appropriate
Mar-10-2021 08:21:54	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

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Site No: 1090

Subject No: 10901140

Generated By: (b) (4)

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(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  If Other, specify:  unk
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-10-2021 08:21:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-10-2021 08:21:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-10-2021 08:21:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Mar-10-2021 08:21:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

Mar-10-2021 08:21:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
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**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Mar-10-2021 14:36:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2021162151	Initial Entry

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**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

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*1. Date of Visit*

Date	Location	User	Value	Reason
Jan-27-2021 14:20:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Jan/22/2021	Initial Entry



**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit  
Trail History

**Form Version:** 10-Dec-2020 02:25

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

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

Date	Location	User	Value	Reason
Jan-27-2021 14:20:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-27-2021 14:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-27-2021 14:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Participant is willing to return for Vaccination 3 Participant is:  eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

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**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Jan-27-2021 14:20:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Jan/25/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Jan-27-2021 14:20:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR A DDITIONAL VACCINATION	Initial Entry

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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*I. Date of Visit*

Date	Location	User	Value	Reason
Jan-29-2021 16:56:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-29-2021 12:10:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	Changed data per query
Jan-29-2021 07:19:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	DM: Kindly consider to update missing SWAB PFE and SAMP TRK forms or else clarify. Thank you.
Jan-27-2021 14:20:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Jan/27/2021	Initial Entry

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INFORMED CONSENT - FURTHER VACCINATION - eCRF  
Audit Trail History

**Form Version:** 10-Dec-2020 02:31

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

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**I. Consent Was:**

Date	Location	User	Value	Reason
Jan-27-2021 14:21:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Jan/27/2021	Initial Entry

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:31

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Jan-27-2021 14:21:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Jan/27/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Jan-27-2021 14:21:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> REPEAT SCREENING 1	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Jan-27-2021 14:21:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1090

Site Name: (1090) Wake Research Associates, LLC

Subject No: 10901140

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Jan-27-2021 14:21:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Jan-27-2021 14:21:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Jan-27-2021 14:21:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Jan/27/2021	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Jan-27-2021 14:21:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Jan-27-2021 14:21:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
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090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1090

Site Name: (1090) Wake Research Associates, LLC

Subject No: 10901140

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

Jan-27-2021 14:21:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 113 <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> NEGATIVE <b>Not Done::</b>	Initial Entry
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**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Jan-27-2021 14:21:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Jan-27-2021 14:21:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Jan-27-2021 14:21:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001**Visit:** V101\_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY  
- eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1090**Site Name:** (1090) Wake Research Associates, LLC**Subject No:** 10901140**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:31[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-29-2021 12:08:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-29-2021 12:08:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-29-2021 12:08:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-29-2021 12:08:32 (UTC-05:00) Eastern 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-29-2021 12:08:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/27/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-29-2021 12:08:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BMN9F6	Initial Entry



Header Text: c4591001

Visit: V101\_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1090

Site Name: (1090) Wake Research Associates, LLC

Subject No: 10901140

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

5.a Sample ID

Date	Location	User	Value	Reason
Jan-29-2021 12:08:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> BMN9F6	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-29-2021 12:09:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BMN9F5</b>	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-29-2021 12:09:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> BMN9F5	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-01-2021 10:03:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BP8G46</b>	Changed Information
Jan-29-2021 12:09:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BP8G45</b>	Initial Entry

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

**5.c Sample ID**

Date	Location	User	Value	Reason
Feb-01-2021 14:12:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Response satisfies query
Feb-01-2021 10:03:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: An swere d	Changed Information
Feb-01-2021 10:03:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry</b> : BP8G 46	Changed Information
Feb-01-2021 09:33:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW7057988;The barcode BP8G45 is recorded for two subjects 10901140 and 10901194. Please review and update CRF as appropriate.
Jan-29-2021 12:09:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry</b> : BP8G 45	Initial Entry

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001**Visit:** V101\_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1090**Site Name:** (1090) Wake Research Associates, LLC**Subject No:** 10901140**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:31[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-29-2021 12:06:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-29-2021 12:06:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-29-2021 12:07:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-29-2021 12:06:55 (UTC-05:00) Eastern 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-29-2021 12:06:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/27/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-29-2021 12:08:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BP8G3L	Changed Information

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

Jan-29-2021 12:07:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BMN9F6	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-29-2021 12:08:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> BP8G3L	Changed Information
Jan-29-2021 12:07:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> BMN9F6	Initial Entry

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1090

Subject No: 10901140

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1090) Wake Research Associates, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Jan-27-2021 14:22:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Jan-27-2021 14:22:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Jan-27-2021 14:22:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Jan-27-2021 14:22:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Jan/27/2021 13:32	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Jan-27-2021 14:22:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
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090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1090

Subject No: 10901140

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1090) Wake Research Associates, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

Jan-27-2021 14:22:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry
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**7. Route:**

Date	Location	User	Value	Reason
Jan-27-2021 14:22:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**8. Actual Dose:**

Date	Location	User	Value	Reason
Jan-27-2021 14:22:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

**9. Unit:**

Date	Location	User	Value	Reason
Jan-27-2021 14:22:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Jan-27-2021 14:22:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-27-2021 14:22:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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*I. Date of Visit*

Date	Location	User	Value	Reason
Feb-18-2021 16:22:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Feb/18/2021	Initial Entry

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

Header Text: c4591001

Visit: V102\_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1090

Site Name: (1090) Wake Research Associates, LLC

Subject No: 10901140

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Feb-18-2021 16:23:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Feb-18-2021 16:23:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Feb-18-2021 16:23:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Feb/18/2021	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Feb-18-2021 16:23:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Feb-18-2021 16:23:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
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090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)



Header Text: c4591001

Visit: V102\_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1090

Site Name: (1090) Wake Research Associates, LLC

Subject No: 10901140

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:31

Feb-18-2021 16:23:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 113 <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> NEGATIVE <b>Not Done::</b>	Initial Entry
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**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Feb-18-2021 16:23:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Feb-18-2021 16:23:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Feb-18-2021 16:23:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001**Visit:** V102\_VAX4**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB -  
eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1090**Site Name:** (1090) Wake Research Associates, LLC**Subject No:** 10901140**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:31[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-19-2021 13:42:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-19-2021 13:42:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-19-2021 13:42:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-19-2021 13:42:39 (UTC-05:00) Eastern 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-19-2021 13:42:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/18/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-19-2021 13:42:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BV0F6P	Initial Entry

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

*5.a Sample ID*

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Feb-19-2021 13:42:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> BV0F6P	Initial Entry

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

Header Text: c4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1090

Subject No: 10901140

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1090) Wake Research Associates, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Feb-18-2021 16:23:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Feb-18-2021 16:23:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Feb-18-2021 16:23:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Feb-18-2021 16:23:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Feb/18/2021 14:34	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Feb-18-2021 16:23:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
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090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

Header Text: c4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1090

Subject No: 10901140

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1090) Wake Research Associates, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:31

Feb-18-2021 16:23:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> RIGHT	Initial Entry
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**7. Route:**

Date	Location	User	Value	Reason
Feb-18-2021 16:23:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**8. Actual Dose:**

Date	Location	User	Value	Reason
Feb-18-2021 16:23:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

**9. Unit:**

Date	Location	User	Value	Reason
Feb-18-2021 16:23:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Feb-18-2021 16:23:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-18-2021 16:23:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

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**1. Subject Status**

Date	Location	User	Value	Reason
Oct-05-2020 08:49:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Aug-12-2020 15:18:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Aug-12-2020 14:56:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Mar-09-2021 20:31:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-09-2021 13:10:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query
Mar-09-2021 06:13:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2021162151 located peritonitis, with pelvic abscess (onset date:04Feb2021)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Feb-19-2021 03:25:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1090

**Subject No:** 10901140

**Generated By:** (b) (4)

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31

Feb-18-2021 13:16:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Feb-18-2021 02:11:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2021162151 ruptured appendix (onset date:08Feb2021)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form
Oct-05-2020 08:49:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/2/2020	Initial Entry
Aug-12-2020 15:18:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/11/2020	Initial Entry
Aug-12-2020 14:56:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/11/2020	Initial Entry

090177e196ae3d7b\Final\Final On: 01-Apr-2021 04:35 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1090

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:31

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*I. Casebook Signature*

Date	Location	User	Value	Reason
Sep-11-2020 13:47:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Wayne Harper (b) (4)	<u>Data Entry:</u> Click Here to Enable	Initial Entry