

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: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[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

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/17/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11091269]
2.	Birth Date:	(b) (6) 1942
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:	

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Aug/17/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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 _____
----	--	-------------------------

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Aug/17/2020
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: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[bipolar disorder]
	Start Date:	Jan/1/1972
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[hypercholesterolemia]
	Start Date:	Jan/1/1999
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[hypertension]
	Start Date:	Apr/1/2019
	Ongoing:	YES

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

1.d	Line/MH Number:	[4]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[hypothyroidism]
	Start Date:	Jan/1/2000
	Ongoing:	YES
1.e	Line/MH Number:	[5]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[memory loss]
	Start Date:	Jan/1/2018
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[sinus ballon surgery]
	Start Date:	May/13/2019
	Ongoing:	NO End Date: May/13/2019

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

1.g	Line/MH Number:	[7]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[sleep disorder]
	Start Date:	Jan/1/1972
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[uterine fibroid's]
	Start Date:	Jan/1/2020
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[post menopausal]
	Start Date:	Jan/1/1995
	Ongoing:	YES

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/17/2020
2.	Weight:	[230.0]
3.	Unit:	LB
4.	Height:	[66.0]
5.	Unit:	in
6.	Body Mass Index:	[37.1]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.6]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/17/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Aug/17/2020
2.	Randomization Number:	[229822]
3.	Randomization Group:	[]

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1109**Site Name:** (1109) Accel Research Sites - Clinical Research Unit**Subject No:** 11091269**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/17/2020
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	[BPXRM3]
5.b	Sample ID	[BPXRM4]
5.c	Sample ID	[BPXRM5]
5.d	Sample ID	[BRWLW6]
5.e	Sample ID	[BRWLW7]

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1109**Site Name:** (1109) Accel Research Sites - Clinical Research Unit**Subject No:** 11091269**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/17/2020
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	[BPXRWB]
-----	-----------	----------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[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/17/2020 17:17
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

Header Text: c4591001

Visit: V2_VAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Sep/10/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/10/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.8]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/10/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1109**Site Name:** (1109) Accel Research Sites - Clinical Research Unit**Subject No:** 11091269**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE	
2.	Sample Type	NASAL_SWAB	
3.	Sample Collected?	YES Date of Collection: Sep/10/2020	Comments
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	Not Applicable _____ []	Comments

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPXRWB]
5.b	Sample ID	[BPXTRT]

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/10/2020 12:08
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

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

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

Site No: 1109 **Site Name:** (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Oct/8/2020
2.	Erroneous Visit	

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1109**Site Name:** (1109) Accel Research Sites - Clinical Research Unit**Subject No:** 11091269**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/8/2020
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	[BR84LP]
5.b	Sample ID	[BSGWFK]
5.c	Sample ID	[BSGWFL]

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: 1109

Site Name: (1109) Accel Research Sites - Clinical
Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 20-Feb-2021 02:17

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Not Started

Site Name: (1109) Accel Research Sites - Clinical
Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (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:** 1109**Site Name:** (1109) Accel Research Sites - Clinical
Research Unit**Subject No:** 11091269**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49**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:** 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:** 1109**Site Name:** (1109) Accel Research Sites - Clinical
Research Unit**Subject No:** 11091269**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49**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: POT_COVID_ILL - New
Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical
Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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?	
----	--	--

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (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: 1109

Site Name: (1109) Accel Research Sites - Clinical
Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Illness Details

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

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

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: 1109

Site Name: (1109) Accel Research Sites - Clinical
Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	
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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:** 1109**Site Name:** (1109) Accel Research Sites - Clinical
Research Unit**Subject No:** 11091269**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49**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: Unplanned - New Unscheduled **Form:** DATE OF VISIT
Visit

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

Site No: 1109 **Site Name:** (1109) Accel Research Sites - Clinical
Research Unit

Subject No: 11091269 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:49

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: 1109 **Site Name:** (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:49

Unplanned Assessments

1.	Assessments	
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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: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Oct/8/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Disposition - Follow-Up

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

Header Text: c4591001

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

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

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical
Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Repeat Swab		
3.	COVID-19 Repeat Swab:	

Header Text: c4591001**Visit:** POT_COVID_REPEAT_SWAB - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB**Form Version:** 10-Oct-2020 15:57 **Form Status:** Not Started**Site No:** 1109**Site Name:** (1109) Accel Research Sites - Clinical Research Unit**Subject No:** 11091269**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	CVA	Nov/17/2020 UNK:UNK	NO End Date Time: Jan/5/2021 UNK: UNK	Repeating Pages
2.	ADVERSE EVENT	2	INJECTION SITE PAIN	Jan/26/2021 U NK:UNK	NO End Date Time: Jan/28/2021 UNK :UNK	Repeating Pages

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[CVA]
4.	Start Date Time:	Nov/17/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/5/2021 UNK:UNK
6.	Toxicity Grade:	3

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1109**Subject No:** 11091269**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Frozen, Not Complete**Site Name:** (1109) Accel Research Sites - Clinical Research Unit**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:49

7.	<p>Is the adverse event serious?</p> <p>If Yes, NOTIFY PFIZER IMMEDIATELY.</p> <p>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).</p>	<p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect? NO</p> <p>Did this serious event result in death? NO</p> <p>Did this serious event require or prolong hospitalization? YES</p> <p>Did this serious event result in persistent or significant disability/incapacity? NO</p> <p>Is this serious event life threatening? NO</p> <p>Other medically important serious event NO</p>
8.	<p>Is this adverse event the result of a study Medication Error?</p> <p>If Yes, record the type of medication error on the Medication Error Log.</p>	NO
9.	<p>Is this event related to study treatment:</p>	<p>NOT RELATED</p> <p>If Not Related to study treatment(s), this event is due to: OTHER</p> <p>If Other, specify: [CEREBREAL ISCHEMIAH]</p>

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED WITH SEQUELAE
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021008476]

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[INJECTION SITE PAIN]
4.	Start Date Time:	Jan/26/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/28/2021 UNK:UNK
6.	Toxicity Grade:	1

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

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Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Form Status: Not Started

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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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	[]

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Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

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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: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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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: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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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?	

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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Radiation Treatment

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

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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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: 1109

Site Name: (1109) Accel Research Sites - Clinical
Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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: 1109

Site Name: (1109) Accel Research Sites - Clinical
Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Vital Signs

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

Vital Signs Details

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

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001**Visit:** Unplanned Vaccination -
Unscheduled**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Version:** 20-Feb-2021 02:14**Form Status:** Not Started**Site No:** 1109**Site Name:** (1109) Accel Research Sites - Clinical
Research Unit**Subject No:** 11091269**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49**Lab Urinalysis**

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

Lab Result

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical
Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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?	

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (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: 1109

Site Name: (1109) Accel Research Sites - Clinical
Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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: 1109

Site Name: (1109) Accel Research Sites - Clinical
Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Contact Outcome

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

Header Text: c4591001

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

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

Site No: 1109 **Site Name:** (1109) Accel Research Sites - Clinical
Research Unit

Subject No: 11091269 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Dec/30/2020
2.	Erroneous Visit	

Header Text: c4591001

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

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

Site No: 1109 **Site Name:** (1109) Accel Research Sites - Clinical
Research Unit

Subject No: 11091269 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: V101_VAX3

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Jan/5/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/5/2021
----	--------------	---

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: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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
----	--	----------------

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (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: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation/Death :	Jan/5/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Frozen, Verified

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Lab Urinalysis

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

Lab Result

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

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001**Visit:** V101_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1109**Site Name:** (1109) Accel Research Sites - Clinical Research Unit**Subject No:** 11091269**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49[eCRF Audit Trail History](#)**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR7Y40]
5.b	Sample ID	[BSGWVG]
5.c	Sample ID	[BSGWVH]

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR7Y3N]
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090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[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/5/2021 12:00
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

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/5/2021
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: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	//
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Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Death Details

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

Cause of Death

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

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Jan/26/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Frozen, Verified

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jan/26/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001**Visit:** V102_VAX4**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1109**Site Name:** (1109) Accel Research Sites - Clinical Research Unit**Subject No:** 11091269**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/26/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR7Y90]
-----	-----------	----------

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[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/26/2021 12:17
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

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

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

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Data Complete, Frozen, Verified

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Contact Outcome

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

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

Contact Outcome

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

Header Text: c4591001

Visit:
FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical
Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Disposition - Treatment

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/8/2020

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: 1109

Site Name: (1109) Accel Research Sites - Clinical
Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical
Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Bruce Rankin	Approved	Mar-10-2021 14:31:08 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, BruceRankin, 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.

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical
Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-18-2020 07:43:54 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[Back to Form](#)

Item	Date	User	Comment
3	Aug-18-2020 09:38:16 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	THIS WAS NOT COMPLETED ON dAY 1 ENTERED IN ERROR

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[Back to Form](#)

Item	Date	User	Comment
4	Aug-18-2020 12:28:27 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	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: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-05-2021 17:39:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical
Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[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
Bruce Rankin	Approved	Mar-10-2021 14:31:08 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, BruceRankin, 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-05-2021 13:58:18 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Bruce Rankin	Approved	Feb-03-2021 14:34:38 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (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: 1109

Site Name: (1109) Accel Research Sites - Clinical
Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Affidavit:

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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-26-2021 14:41:35 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Bruce Rankin	Approved	Jan-21-2021 16:10:01 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (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: 1109

Site Name: (1109) Accel Research Sites - Clinical
Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Affidavit:

By my dated signature below, I, BruceRankin, 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-20-2021 22:31:51 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Bruce Rankin	Approved	Jan-20-2021 14:34:11 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (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: 1109

Site Name: (1109) Accel Research Sites - Clinical
Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Affidavit:

By my dated signature below, I, BruceRankin, 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-05-2021 17:38:23 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Bruce Rankin	Approved	Oct-21-2020 14:54:17 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Status: Data Complete, Signed, Verified

Site Name: (1109) Accel Research Sites - Clinical
Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

Affidavit:

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

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-18-2020 07:40:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-18-2020 07:40:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Aug-18-2020 07:41:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Aug/17/2020	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Aug-18-2020 07:40:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11091269	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-18-2020 07:40:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) /1942	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-18-2020 07:43:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
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090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Aug-18-2020 07:43:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry
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5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Aug-18-2020 07:43:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Aug-18-2020 07:43:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/17/2020	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-18-2020 07:44:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/17/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-18-2020 07:44:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-18-2020 07:44:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1109**Site Name:** (1109) Accel Research Sites - Clinical Research Unit**Subject No:** 11091269**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49[Back to Form](#)*1.a*

Date	Location	User	Value	Reason
Aug-18-2020 07:44:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 1 Medical History Term: bipolar disorder Start Date: Jan/1/1972 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 07:44:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-18-2020 07:44:51 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: bipolar disorder	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

& Canada)

1.a Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 07:44:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/1/1972	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-18-2020 07:44:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Aug-18-2020 07:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 2 Number: Medical H hyperchol istory Ter esterolem m: ia Start Date Jan/1/199 : 9	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

			Ongoing: YES	
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 07:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-18-2020 07:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: hypercholesterolemia	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 07:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/1/1999	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Aug-18-2020 07:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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I.c

Date	Location	User	Value	Reason
Aug-18-2020 07:45:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 3 mber: Medical Hist hyperten ory Term: sion Start Date: Apr/1/2 019 Ongoing: YES	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

1.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 07:45:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Aug-18-2020 07:45:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: hypertension	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 07:45:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Apr/1/2019	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
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090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Aug-18-2020 07:45:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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1.d

Date	Location	User	Value	Reason
Aug-18-2020 07:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 4 Medical History Term: hypothyroidism Start Date: Jan/1/2000 Ongoing: YES	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

1.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 07:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Aug-18-2020 07:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: hypothyroidism	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 07:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/1/2000	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Aug-18-2020 07:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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I.e

Date	Location	User	Value	Reason
Aug-18-2020 07:46:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 5 mber: Medical Hist memor ory Term: y loss Start Date: Jan/1/2 018 Ongoing: YES	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

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Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

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1.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 07:46:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 22:20:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-24-2020 07:45:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	I can confirm
Aug-23-2020 19:55:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: memory loss: Please can you confirm subject meets all inclusion and exclusion criteria as a result of this

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Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

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				medhx? Thanks
Aug-18-2020 07:46:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: memory loss	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 07:46:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/1/2018	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Aug-18-2020 07:46:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Aug-18-2020 07:47:33	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

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(UTC-05:00)
Eastern Time (US
& Canada)

Line/MH Number:	6
Medical History Term:	sinus balloon surgery
Start Date:	May/13/2019
Ongoing:	NO
End Date:	May/13/2019

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

1.f Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 07:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Aug-18-2020 07:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: sinus ballon surgery	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 07:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: May/13/2019	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
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090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Aug-18-2020 07:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: May/13/2019	Initial Entry
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I.g

Date	Location	User	Value	Reason
Aug-18-2020 07:48:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 7 Medical History Term: sleep disorder Start Date: Jan/1/1972 Ongoing: YES	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

1.g Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 07:48:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

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

Date	Location	User	Value	Reason
Aug-18-2020 07:48:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: sleep disorder	Initial Entry

1.g Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 07:48:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/1/1972	Initial Entry

1.g Ongoing:

Date	Location	User	Value	Reason
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090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

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Aug-18-2020 07:48:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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1.h

Date	Location	User	Value	Reason
Aug-18-2020 07:48:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 8 Medical History Term: uterine fibroid's Start Date: Jan/1/2020 Ongoing: YES	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

1.h Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 07:48:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Aug-18-2020 07:48:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: uterine fibroid's	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 07:48:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/1/2020	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
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090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Aug-18-2020 07:48:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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1.i

Date	Location	User	Value	Reason
Aug-18-2020 07:49:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 9 Medical History Term: post menopausal Start Date: Jan/1/1995 Ongoing: YES	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

1.i Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 07:49:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

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

Date	Location	User	Value	Reason
Aug-18-2020 07:49:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: post menopausal	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 07:49:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/1/1995	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Aug-18-2020 07:49:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Date:

Date	Location	User	Value	Reason
Aug-18-2020 07:52:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/17/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-18-2020 07:52:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 230.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-18-2020 07:52:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LB	Initial Entry

4. Height:

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Date	Location	User	Value	Reason
Aug-18-2020 07:52:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 66.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-18-2020 07:52:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-18-2020 07:52:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 37.1	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-18-2020 07:52:40 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Ide 1	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L **Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History
Form Version: 30-Jul-2020 21:28 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1109 **Site Name:** (1109) Accel Research Sites - Clinical Research Unit
Subject No: 11091269 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:49

Eastern Time (US & Canada)			ntifier:: Temperatu 97.6 re: Temperatu F re Unit: Temperatu ORAL re Location CAVIT :: Y	
Aug-18-2020 07:52:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifi 1 er:: Temperature: 97. 6 Temperature U F nit: Temperature L ocation::	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-18-2020 07:52:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Aug-18-2020 07:52:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.6	Initial Entry
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7.a Unit:

Date	Location	User	Value	Reason
Aug-18-2020 07:52:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-18-2020 07:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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1. Lab Panel:

Date	Location	User	Value	Reason
Aug-18-2020 07:52:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-18-2020 07:52:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-18-2020 07:52:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/17/2020	Initial Entry

4. Laboratory Name and Address (Derived)

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

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: 1109

Site Name: (1109) Accel Research Sites - Clinical
Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Date	Location	User	Value	Reason
Aug-18-2020 07:52:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Aug-18-2020 07:52:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-18-2020 07:52:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined I dentifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: Not Done NOT DON :: E	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

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: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-18-2020 07:52:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-18-2020 07:52:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Aug-18-2020 07:52:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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1. Randomization Date :

Date	Location	User	Value	Reason
Aug-18-2020 07:52:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/17/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-18-2020 07:52:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 229822	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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1. Data Origin

Date	Location	User	Value	Reason
Aug-18-2020 07:53:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-18-2020 07:53:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-18-2020 09:40:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-18-2020 07:53:05	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (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:** 1109**Site Name:** (1109) Accel Research Sites - Clinical Research Unit**Subject No:** 11091269**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-18-2020 07:53:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/17/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-18-2020 09:40:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BPXR D: M3	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-18-2020 09:40:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPXRM3	Initial Entry

5.b

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: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Date	Location	User	Value	Reason
Aug-18-2020 09:40:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BPXR D: M4	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-18-2020 09:40:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPXRM4	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-18-2020 09:41:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BPXR D: M5	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

5.c Sample ID

Date	Location	User	Value	Reason
Aug-18-2020 09:41:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPXRM5	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-18-2020 09:41:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BRWL D: W6	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-18-2020 09:41:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRWLW6	Initial Entry

5.e

Date	Location	User	Value	Reason
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090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (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: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Aug-18-2020 09:42:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BRWL D: W7	Initial Entry
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5.e Sample ID

Date	Location	User	Value	Reason
Aug-18-2020 09:42:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRWLW7	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1109**Site Name:** (1109) Accel Research Sites - Clinical Research Unit**Subject No:** 11091269**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-18-2020 07:53:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-18-2020 07:53:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-18-2020 09:39:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-18-2020 07:53:13	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

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: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-18-2020 07:53:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/17/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-18-2020 09:39:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BPXRW D: B	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-18-2020 09:39:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPXRWB	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-18-2020 07:53:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-18-2020 07:53:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-18-2020 07:53:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
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090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

Aug-18-2020 07:53:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/17/2020 17:17	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-18-2020 07:53:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-18-2020 07:53:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-18-2020 07:53:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-18-2020 07:53:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-18-2020 07:53:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-07-2020 03:32:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-04-2020 10:05:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-04-2020 10:05:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Transcription Error
Sep-03-2020 11:47:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	eDiary: REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT is 'Yes' however VAX 1 eDiary records are

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

				not available for the subject. Please verify and update. Else, confirm in query response appropriately.
Aug-18-2020 07:53:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: YES - REAC TOGENICIT Y E-DIARY COLLECTE D FOR THIS SUBJECT	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-12-2020 05:49:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed per SITE response
Sep-11-2020 11:58:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	PROTOCOL DEVIATION WRITTEN AND FILED IN CHART
Sep-11-2020 04:58:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	PDQ: Date of visit at this visit is out of window (1 day) from Date of visit (17/Aug /2020) at V1D1VX1L visit. Please reconcile and update accordingly, else confirm date is correct as is.

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

Sep-10-2020 14:43:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/10/2020	Initial Entry
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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1. Date:

Date	Location	User	Value	Reason
Sep-10-2020 14:44:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/10/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-10-2020 14:44:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Temperature: 97.8 Temperature Unit: Temperature Location: ORAL CAVITY Y	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-10-2020 14:44:38 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Eastern Time (US & Canada)				
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2.a Temperature:

Date	Location	User	Value	Reason
Sep-10-2020 14:44:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.8	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-10-2020 14:44:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-10-2020 14:44:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (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: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-10-2020 14:44:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-10-2020 14:44:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-10-2020 14:44:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/10/2020	Initial Entry

4. Laboratory Name and Address (Derived)

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (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: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Date	Location	User	Value	Reason
Sep-10-2020 14:44:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-10-2020 14:44:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-10-2020 14:44:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined Identifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: Not Done NOT DON :: E	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (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: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-10-2020 14:44:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-10-2020 14:44:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-10-2020 14:44:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (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: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Data Origin

Date	Location	User	Value	Reason
Aug-18-2020 09:30:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-18-2020 09:30:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-11-2020 09:51:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Closed	Close Auto Query
Sep-11-2020 09:51:29	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Transcription Error

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (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: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	Date of Collection: Sep/10/2020	
Sep-11-2020 09:51:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Opened	Response to "Sample Collected?" is No, but Barcodes are present on the page.
Aug-19-2020 13:55:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Closed by DM: (b) (6)
Aug-18-2020 12:28:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Changed data per query
Aug-18-2020 09:36:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (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: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

				protocol, please provide reason' is missing. Please review and update as appropriate.
Aug-18-2020 09:33:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Aug-18-2020 09:33:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: 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-18-2020 09:33:00 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (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: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Eastern Time (US & Canada)				
Aug-18-2020 09:33:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Transcription Error
Aug-18-2020 09:32:28 (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-18-2020 09:30:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-18-2020 09:30:23 (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-18-2020 09:30:23	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (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: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	Date of Collection: Aug/17/2020
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4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Aug-18-2020 12:28:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Aug-18-2020 09:36:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Aug-18-2020 09:33:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Entered in error	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-18-2020 09:32:28 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample BPXR	Transcription Error (DELETED)

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (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: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Eastern Time (US & Canada)			ID: WB	
Aug-18-2020 09:30:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPXR WB	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-18-2020 09:32:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPXRWB	Transcription Error (DELETED)
Aug-18-2020 09:30:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPXRWB	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-11-2020 09:51:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPXTR T	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (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: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

5.b Sample ID

Date	Location	User	Value	Reason
Sep-11-2020 09:51:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPXTRT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-10-2020 14:45:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-10-2020 14:45:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-10-2020 14:45:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
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090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Sep-10-2020 14:45:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/10/2020 12:08	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-10-2020 14:45:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-10-2020 14:45:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-10-2020 14:45:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-10-2020 14:45:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 14:45:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT - eCRF Audit Trail History

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

Site No: 1109 **Site Name:** (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:49

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-08-2020 13:04:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/8/2020	Initial Entry

Header Text: c4591001

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

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

Site No: 1109 **Site Name:** (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:49

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1. Data Origin

Date	Location	User	Value	Reason
Oct-08-2020 13:04:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-08-2020 13:04:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-08-2020 16:40:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-08-2020 13:04:49	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1109**Site Name:** (1109) Accel Research Sites - Clinical Research Unit**Subject No:** 11091269**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-08-2020 13:04:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection : Oct/8/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-08-2020 16:40:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BR84L D: P	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-08-2020 16:40:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR84LP	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: 1109 **Site Name:** (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:49

5.b

Date	Location	User	Value	Reason
Oct-08-2020 16:49:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BSGWF D: K	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-08-2020 16:49:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSGWFK	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-08-2020 16:49:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BSGWF D: L	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

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

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

Site No: 1109 **Site Name:** (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:49

5.c Sample ID

Date	Location	User	Value	Reason
Oct-08-2020 16:49:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSGWFL	Initial Entry

Header Text: c4591001

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

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

Site No: 1109 **Site Name:** (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:49

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-08-2020 13:05:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/8/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-08-2020 13:05:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-08-2020 13:05:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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Date	Location	User	Value	Reason
Jan-06-2021 14:16:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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Date	Location	User	Value	Reason
Mar-05-2021 09:36:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Not Complete

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Category:

Date	Location	User	Value	Reason
Jan-06-2021 14:16:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-06-2021 14:16:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-02-2021 16:23:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Query closed; will follow for requested clinical course information.
Feb-26-2021 19:51:47	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Hospital never sent records

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Site No: 1109

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(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		
Jan-22-2021 12:26:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	CLINICAL Thank you; please submit the presenting symptoms, examination findings, any imaging, description of sequelae remaining at recovery, & other relevant clinical info when Med Records arrive
Jan-15-2021 16:37:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Waiting for records
Jan-08-2021 12:17:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL Please submit a safety update for SAE of CVA with the presenting symptoms,

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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, Frozen, Not Complete**Site No:** 1109**Site Name:** (1109) Accel Research Sites - Clinical Research Unit**Subject No:** 11091269**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49

				examination findings, any imaging, description of sequelae remaining at recovery, & other relevant clinical information
Jan-06-2021 14:16:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CVA	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-06-2021 14:16:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/17/2020 UNK:U NK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-06-2021 14:16:15 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time:	Initial Entry

Header Text: c4591001

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Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Eastern Time (US & Canada)

Jan/5/2021 UNK:
UNK

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-23-2021 19:41:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-05-2021 13:58:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Feb-05-2021 13:58:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Changed Information
Jan-22-2021 17:25:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	CLINICAL Thank you; many SAE criteria can be reported. However, when an AE is Grade 4 it is considered life-threatening, and

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				life-threatening is required to be a SAE severity criterion. (If no life-threatening, then down-grade from Grade 4 intensity).
Jan-22-2021 13:35:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	SAE criteria is also considered prolonged hospital stay
Jan-22-2021 12:37:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	Clinical Per Protocol Sect 8.2.2.3 Systemic post-Vaccination AEs, potentially life threatening=grade 4; other standard AEs see Sect 10.3.3. Assessment of Intensity table [grade 4=life threatening]. Please update Gr 4/SAE criteria to harmonize reporting

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Jan-15-2021 16:13:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Per PI leave as is
Jan-08-2021 12:15:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL Toxicity grade for event CVA is 4; however, life threatening is not selected as a serious criterion. Please review for immediate life threatening severity, harmonize reporting, and update in the appropriate location.
Jan-06-2021 14:16:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization;

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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
Jan-22-2021 12:25:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Query closed; will follow for requested COVID test information.
Jan-15-2021 16:51:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Waiting for records
Jan-11-2021 02:30:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query can be addressed internally
Jan-08-2021 12:15:46 (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 [#2021008476] to document if

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				COVID testing was performed (YES/NO or info not available) and if yes, the date and results.
Jan-06-2021 14:16:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE CVA: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-06-2021 14:16:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO	Initial Entry

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Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

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			<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>NO</p> <p>Other medically important serious event</p> <p>NO</p>	
--	--	--	---	--

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
Jan-06-2021 14:16:15	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

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(UTC-05:00)
Eastern Time (US
& Canada)

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

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-18-2021 02:12:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-15-2021 10:00:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Jan-15-2021 10:00:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> CEREBREAL ISCHEMIA	New Information

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Form Status: Data Complete, Frozen, Not Complete

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Subject Initials: ---

Generated By: (b) (4)

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			AH	
Jan-08-2021 02:14:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly consider updating 'If Not Related to study treatment(s)' missing field. Thank you.
Jan-06-2021 14:16:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-06-2021 14:16:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-06-2021 14:16:15 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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Subject No: 11091269

Subject Initials: ---

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& Canada)

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-06-2021 14:16:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Jan-06-2021 14:16:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED WITH SEQUELAE	Initial Entry

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

Date	Location	User	Value	Reason
Jan-06-2021 14:16:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

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Generated By: (b) (4)

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Date	Location	User	Value	Reason
Jan-20-2021 22:31:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021008476	Initial Entry

Header Text: c4591001

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1. Category:

Date	Location	User	Value	Reason
Mar-05-2021 09:36:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Mar-05-2021 09:36:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-05-2021 09:36:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: INJECTION SITE P AIN	Initial Entry

4. Start Date Time:

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Subject Initials: ---

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Date	Location	User	Value	Reason
Mar-05-2021 09:36:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/26/2021 UNK:U NK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-05-2021 09:36:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/28/2021 UNK :UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-05-2021 09:36:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization;

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Generated By: (b) (4)

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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 09:36:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Mar-05-2021 09:36:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-05-2021 09:36:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Date	Location	User	Value	Reason
Mar-05-2021 09:36:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-05-2021 09:36:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-05-2021 09:36:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Mar-05-2021 09:36:03 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RES OLVED	Initial Entry

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Header Text: c4591001

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Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

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Subject Initials: ---

Generated By: (b) (4)

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Eastern Time (US & Canada)

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

Date	Location	User	Value	Reason
Mar-05-2021 09:36:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

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

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

Site No: 1109 **Site Name:** (1109) Accel Research Sites - Clinical
Research Unit

Subject No: 11091269 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:49

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-05-2021 17:38:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/30/2020	Initial Entry

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Header Text: c4591001

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

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

Site No: 1109 **Site Name:** (1109) Accel Research Sites - Clinical
Research Unit

Subject No: 11091269 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:49

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

Date	Location	User	Value	Reason
Jan-05-2021 17:43:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-05-2021 17:38:42 (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-05-2021 17:38:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willin g to return for Vacci nation 3 Participant is: eligible per local /national recom mendations and	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

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

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

Site No: 1109 **Site Name:** (1109) Accel Research Sites - Clinical
Research Unit

Subject No: 11091269 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:49

			confirmed to have received only placebo at Vaccination 1/2	
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Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-05-2021 17:39:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/5/2021	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER
VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1109) Accel Research Sites - Clinical
Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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1. Consent Was:

Date	Location	User	Value	Reason
Jan-05-2021 17:39:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consequence nt Obtained Jan/5/2021	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Jan-05-2021 17:41:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/5/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-05-2021 17:41:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-05-2021 17:41:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001**Visit:** V101_VAX3**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:23**Form Status:** Data Complete, Frozen, Verified**Site No:** 1109**Site Name:** (1109) Accel Research Sites - Clinical Research Unit**Subject No:** 11091269**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Jan-05-2021 17:41:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Jan-05-2021 17:41:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-05-2021 17:41:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/5/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Date	Location	User	Value	Reason
Jan-05-2021 17:41:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Jan-05-2021 17:41:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Jan-05-2021 17:41:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined Identifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: Not Done NOT DON :: E	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical
Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

6.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-05-2021 17:41:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jan-05-2021 17:41:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Jan-05-2021 17:41:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (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: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Data Origin

Date	Location	User	Value	Reason
Jan-05-2021 17:42:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-05-2021 17:42:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-06-2021 07:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-06-2021 05:53:21	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (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:** 1109**Site Name:** (1109) Accel Research Sites - Clinical Research Unit**Subject No:** 11091269**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-05-2021 17:42:08 (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-05-2021 17:42:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/5/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-06-2021 07:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BR7Y4 D: 0	Initial Entry

5.a Sample ID

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: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Date	Location	User	Value	Reason
Jan-06-2021 07:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR7Y40	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-06-2021 07:00:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BSGWV D: G	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-06-2021 07:00:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSGWVG	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-06-2021 07:00:56 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BSGWV	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (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: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Eastern Time (US & Canada)			D: H	
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5.c Sample ID

Date	Location	User	Value	Reason
Jan-06-2021 07:00:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSGWVH	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (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: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Data Origin

Date	Location	User	Value	Reason
Jan-05-2021 17:42:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-05-2021 17:42:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-06-2021 07:01:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-06-2021 05:53:21	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Opened	'Sample Collected?' is

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (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: 1109 **Site Name:** (1109) Accel Research Sites - Clinical Research Unit
Subject No: 11091269 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:49

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-05-2021 17:42:20 (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-05-2021 17:42:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/5/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-06-2021 07:01:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BR7Y3 D: N	Initial Entry

5.a Sample ID

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: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Date	Location	User	Value	Reason
Jan-06-2021 07:01:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR7Y3N	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-05-2021 17:42:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-05-2021 17:42:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-05-2021 17:42:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
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090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Jan-05-2021 17:42:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/5/2021 12:00	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-05-2021 17:42:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-05-2021 17:42:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jan-05-2021 17:42:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-05-2021 17:42:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-05-2021 17:42:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-05-2021 17:42:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Jan-05-2021 17:42:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-05-2021 17:43:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/5/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-05-2021 17:43:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILIT Y FOR ADDITIONA L VACCINATION	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-26-2021 14:41:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/26/2021	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-26-2021 14:42:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Jan-26-2021 14:42:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-26-2021 14:42:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/26/2021	Initial Entry

4. Laboratory Name and Address (Derived)

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Date	Location	User	Value	Reason
Jan-26-2021 14:42:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Jan-26-2021 14:42:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Jan-26-2021 14:42:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined Identifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: Not Done NOT DON :: E	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

6.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-26-2021 14:42:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jan-26-2021 14:42:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Jan-26-2021 14:42:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (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: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Data Origin

Date	Location	User	Value	Reason
Jan-26-2021 14:42:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-26-2021 14:42:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-27-2021 15:31:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-26-2021 14:42:21	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (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: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-26-2021 14:42:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection : Jan/26/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-27-2021 15:31:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample I BR7Y9 D: 0	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-27-2021 15:31:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR7Y90	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-26-2021 14:42:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-26-2021 14:42:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-26-2021 14:42:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
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090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Jan-26-2021 14:42:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/26/2021 12:17	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-26-2021 14:42:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-26-2021 14:42:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jan-26-2021 14:42:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-26-2021 14:42:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-26-2021 14:42:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-26-2021 14:42:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Jan-26-2021 14:43:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-08-2021 11:34:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Closed	Response satisfies query
Mar-08-2021 06:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Answered	Changed data per query
Mar-08-2021 05:38:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Opened	DM: Patient completed Vaccination 3 visit through the 1-month post vaccination visit after the Vaccination 4. Please complete treatment disposition CRF and update date of EOT2 to match date of

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

				visit at visit 103.
Mar-04-2021 09:30:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Mar/1/2021	Initial Entry

Header Text: c4591001

Visit: V103_MONTH1

Form: CONTACT OUTCOME - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Contact Type:

Date	Location	User	Value	Reason
Mar-04-2021 09:31:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Mar-04-2021 09:31:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Contact: Mar/1/2021	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit:
FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit
Trail History

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical
Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Mar-08-2021 06:29:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/1/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-08-2021 06:29:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: OPEN LABEL TREAT MENT	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-08-2021 06:29:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Subject Status

Date	Location	User	Value	Reason
Oct-08-2020 13:05:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-18-2020 07:52:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-18-2020 07:44:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-08-2020 13:05:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/8/2020	Initial Entry
Aug-18-2020	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1109

Site Name: (1109) Accel Research Sites - Clinical Research Unit

Subject No: 11091269

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

07:52:57 (UTC-05:00) Eastern Time (US & Canada)		(autocalc)	Aug/17/2020	
Aug-18-2020 07:44:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/17/2020	Initial Entry

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1109

Subject No: 11091269

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1109) Accel Research Sites - Clinical
Research Unit

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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1. Casebook Signature

Date	Location	User	Value	Reason
Oct-21-2020 14:53:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Click Here to Enable	Initial Entry

090177e196ae3ede\Final\Final On: 01-Apr-2021 05:03 (GMT)