

**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:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Cohort Selection**

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

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

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** MAIN INFORMED CONSENT

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/2/2020
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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:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[10951206]
2.	Birth Date:	(b) (6) /1957
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** DATE OF VISIT

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

**Form Comments**

**Inclusion Criteria Not Met**

1.	Description of Inclusion Criterion Not Met	Not Applicable
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**Exclusion Criteria Met**

2.	Description of Exclusion Criterion Met	Not Applicable
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**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation/Death	Sep/2/2020
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:** 1095

**Subject No:** 10951206

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[COPD]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Coronary Artery Disease]
	Start Date:	UNK/UNK/2012
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Degenerative Disc Disease]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypercholesterolemia]
	Start Date:	UNK/UNK/2012
	Ongoing:	YES

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	UNK/UNK/2012
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Irritable Bowel Syndrome]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Seasonal Allergies]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Cervical fusion]
	Start Date:	UNK/UNK/2012
	Ongoing:	NO End Date: UNK/UNK/2012
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Cyst Kidney]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES

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**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Kidney stones]
	Start Date:	UNK/UNK/2015
	Ongoing:	NO End Date: UNK/UNK/2015
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Right Hip Replacement]
	Start Date:	UNK/UNK/2010
	Ongoing:	NO End Date: UNK/UNK/2010
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Transurethral resection of the prostate]
	Start Date:	UNK/UNK/2017
	Ongoing:	NO End Date: UNK/UNK/2017
1.m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Sulfa drug allergy (hives)]
	Start Date:	UNK/UNK/1988
	Ongoing:	YES

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**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

1.n	Line/MH Number:	[14]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Spinal Cord stimulator Insertion]
	Start Date:	UNK/UNK/2009
	Ongoing:	YES
1.o	Line/MH Number:	[15]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[right hip pain]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES
1.p	Line/MH Number:	[16]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Benign prostatic hyperplasia]
	Start Date:	UNK/UNK/2017
	Ongoing:	NO End Date: UNK/UNK/2017

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**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** VITAL SIGNS - BASELINE

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/2/2020
2.	Weight:	[68.9]
3.	Unit:	kg
4.	Height:	[165.5]
5.	Unit:	cm
6.	Body Mass Index:	[25.2]

**Vital Signs Details**

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

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**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** RANDOMIZATION

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Sep/2/2020
2.	Randomization Number:	[249910]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

**eCRF Audit Trail History**

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BPY2YJ]
5.b	Sample ID	[BPY2YK]
5.c	Sample ID	[BPY2YL]
5.d	Sample ID	[BPCT4R]

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**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951206

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

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

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP3BJM]
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090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** VACCINATION

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

**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/2/2020 12:07
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

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**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** DATE OF VISIT

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Sep/24/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 15-Sep-2020 21:54

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** VITAL SIGNS - TEMP

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/24/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[98.5]
	Unit:	F
	Temperature Location:	ORAL CAVITY

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1095

**Subject No:** 10951206

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

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

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

**eCRF Audit Trail History**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/24/2020
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	[BP1N3W]
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090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** VACCINATION

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

**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/24/2020 10:45
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

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (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:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Oct/23/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

**eCRF Audit Trail History**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/23/2020
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	[BRDFZM]
5.b	Sample ID	[BRDFZN]
5.c	Sample ID	[BRDFZP]
5.d	Sample ID	[BPLJW1]
5.e	Sample ID	[BPLJW0]

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**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:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	
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090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)

**Header Text:** c4591001

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

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

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

**Form Status:** Not Started

**Site No:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**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:	[ ]
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**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:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**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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090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**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:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**Health Care Utilization**

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

**Health Care Utilization Other**

2.	Other Type of Practitioner Specify:	[ ]
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**Health Care Utilization**

3.	Has the subject been hospitalized due to potential COVID-19 illness?	
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**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:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**Illness Details**

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

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**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:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**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:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**Unplanned Assessments**

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



**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT

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

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

**Site No:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation/Death :	Oct/23/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Incomplete, Verified

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Disposition - Follow-Up**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New  
Unscheduled Visit

**Form:** DATE OF VISIT - REPEAT SWAB

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

**Form Status:** Not Started

**Site No:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

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

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New  
Unscheduled Visit

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

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

**Form Status:** Not Started

**Site No:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**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:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	osteoporosis right hip	Sep/22/2020 UNK:UNK	NO End Date Time:  Nov/15/2020 UNK:UNK	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	ruptured blood vessel behind Left eye	Nov/17/2020 UNK:UNK	NO End Date Time:  Nov/18/2020 UNK:UNK	<a href="#">Repeating Pages</a>

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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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)	[osteoporosis right hip]
4.	Start Date Time:	Sep/22/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/15/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [wear/aging]

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1095

Subject No: 10951206

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1095) Tekton Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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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)	[ruptured blood vessel behind Left eye]
4.	Start Date Time:	Nov/17/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/18/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES  Is this serious event associated with congenital anomaly or birth defect? NO  Did this serious event result in death? NO  Did this serious event require or prolong hospitalization? YES  Did this serious event result in persistent or significant disability/incapacity? NO  Is this serious event life threatening? NO  Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [epistaxis]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021015538]

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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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:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Not Started

**Site No:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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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:	//

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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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?	

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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**Radiation Treatment**

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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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:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**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:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**Vital Signs**

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

**Vital Signs Details**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**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?	

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (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:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**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:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**Contact Outcome**

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



**Header Text:** c4591001

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

**Form:** DATE OF VISIT

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

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

**Site No:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/7/2021
2.	Erroneous Visit	

**Header Text:** c4591001

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

**Form:** FURTHER VACCINATION CONFIRMATION

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

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

**Site No:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** DATE OF VISIT

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** INFORMED CONSENT - FURTHER VACCINATION

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Informed Consent - Further Vaccination**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/8/2021
----	--------------	---

**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:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**Form Comments**

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

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

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1095

**Subject No:** 10951206

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

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

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Disposition - Screening for Further Vaccination**

1.	Date of Completion/Discontinuation/Death :	Jan/8/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

**eCRF Audit Trail History**

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP1T9T]
5.b	Sample ID	[BP1T9V]
5.c	Sample ID	[BP1T9W]
5.d	Sample ID	[BPCTGC]

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**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1095

**Subject No:** 10951206

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

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

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

**eCRF Audit Trail History**

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP1NCN]
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090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)



**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** VACCINATION

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

**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/8/2021 15:11
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

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** TREATMENT UNBLINDED

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Jan/7/2021
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:** 1095

**Subject No:** 10951206

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

**Form:** WITHDRAWAL OF CONSENT

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[Form Comments](#)

[eCRF Audit Trail History](#)

**Withdrawal Of Consent**

			<a href="#">Comments</a>
1.	Withdrawal of Consent Date :	Not Applicable <hr/> //	

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** DEATH DETAILS CODED

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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

**Death Details**

1.	Date of Collection / Notification of Death:	Not Applicable _____ //	<a href="#">Comments</a>
----	---	-------------------------------	--------------------------

**Cause of Death**

2.	Cause of Death Status:	Not Applicable _____
	Cause of Death:	Not Applicable _____ [ ]

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** DATE OF VISIT

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/28/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1095

**Subject No:** 10951206

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

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

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

**eCRF Audit Trail History**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/28/2021
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	[BR0VDK]
-----	-----------	----------

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** VACCINATION

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

**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/28/2021 13:14
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

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** DATE OF VISIT

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Date of Visit**

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



**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** CONTACT OUTCOME

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Contact Outcome**

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Feb/26/2021
3.	Comments:	[ ]

**Header Text:** c4591001

**Visit:** V104\_MONTH6

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

**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:** 1095

**Subject No:** 10951206

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

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

**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:** 1095

**Subject No:** 10951206

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

**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:** 1095

**Subject No:** 10951206

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

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

**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:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation/Death :	Feb/26/2021
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:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/23/2020

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Data Complete, Verified

**Site No:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

[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, Verified

**Site No:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

[Audit Trail](#)

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
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**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951206

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

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

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Sep-02-2020 11:53:17 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Jan-08-2021 18:17:28 (UTC-06:00) Central Time (US & Canada)	Kate Jurek (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** WITHDRAWAL OF CONSENT - Comments

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

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

**Site No:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Jan-08-2021 18:15:14 (UTC-06:00) Central Time (US & Canada)	Kate Jurek (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** Disposition

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** WITHDRAWAL OF CONSENT - Comments

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Jan-08-2021 18:15:14 (UTC-06:00) Central Time (US & Canada)	Kate Jurek (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** DEATH DETAILS CODED - Comments

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

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

**Site No:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Jan-08-2021 18:15:34 (UTC-06:00) Central Time (US & Canada)	Kate Jurek (b) (4)	Not Applicable

**Header Text:** c4591001

**Visit:** Disposition

**Form:** DEATH DETAILS CODED - Comments

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

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

**Site No:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Jan-08-2021 18:15:34 (UTC-06:00) Central Time (US & Canada)	Kate Jurek (b) (4)	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, Verified

**Site No:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
Kate Jurek	N/A	Jan-08-2021 18:14:47 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

**Affidavit:**

N/A

Paul Pickrell	Approved	Nov-07-2020 16:22:23 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
---------------	----------	---	------	--------

**Affidavit:**

By my dated signature below, I, PaulPickrell, 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.

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)



**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:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Sep-02-2020 11:52:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 11:52:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1095

**Subject No:** 10951206

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

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

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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*I. Consent Was:*

Date	Location	User	Value	Reason
Sep-02-2020 11:52:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Sep/2/2020	Initial Entry

Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1095

Subject No: 10951206

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Subject ID**

Date	Location	User	Value	Reason
Sep-02-2020 11:52:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	<b>Data Entry:</b> 10951206	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Sep-02-2020 11:52:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	<b>Data Entry:</b> (b) (6) /1957	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Sep-02-2020 11:53:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Sep-02-2020 11:52:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 11:52:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951206

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

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

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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*1. Date of Visit*

Date	Location	User	Value	Reason
Sep-02-2020 11:53:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/2/2020	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951206

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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

Date	Location	User	Value	Reason
Sep-02-2020 11:53:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sep/2/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Sep-02-2020 11:53:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Sep-02-2020 11:53:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> COMPLETED	Initial Entry

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951206

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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*1.a*

Date	Location	User	Value	Reason
Sep-02-2020 12:28:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number 1</b> : <b>Medical History T COPD</b> <b>erm:</b> <b>Start Date:</b> UNK/UNK/2 015 <b>Ongoing:</b> YES	Initial Entry

*1.a Line/MH Number:*

Date	Location	User	Value	Reason
Sep-02-2020 12:28:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 12:28:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COPD	Initial Entry

*1.a Start Date:*

Date	Location	User	Value	Reason
Sep-02-2020 12:28:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2015	Initial Entry

*1.a Ongoing:*

Date	Location	User	Value	Reason
Sep-02-2020 12:28:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951206

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

I.b

Date	Location	User	Value	Reason
Sep-02-2020 12:29:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Num 2 <b>ber:</b> Medical Histor Coronary Artery y Term: Disease Start Date: UNK/UNK/201 2 Ongoing: YES	Initial Entry

I.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-02-2020 12:29:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 12:29:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Coronary Artery Disease	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Sep-02-2020 12:29:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2012	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Sep-02-2020 12:29:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

I.c

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951206

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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Date	Location	User	Value	Reason
Sep-02-2020 12:31:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Num</b> 3 <b>ber:</b> <b>Medical Histor</b> Degenerative Dis <b>y Term:</b> c Disease <b>Start Date:</b> UNK/UNK/2000 <b>Ongoing:</b> YES	Initial Entry

*I.c Line/MH Number:*

Date	Location	User	Value	Reason
Sep-02-2020 12:31:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 12:31:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Degenerative Disc Disease	Initial Entry

*I.c Start Date:*

Date	Location	User	Value	Reason
Sep-02-2020 12:31:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2000	Initial Entry

*I.c Ongoing:*

Date	Location	User	Value	Reason
Sep-02-2020 12:31:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

*I.d*

Date	Location	User	Value	Reason
Sep-02-2020 12:31:48	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Initial Entry

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951206

Generated By: (b) (4)

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Site Name: (1095) Tekton Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

(UTC-06:00) Central Time (US & Canada)		(autocalc)	<b>Line/MH Number:</b> 4 <b>Medical History Term:</b> Hypercholesterolemia <b>Start Date:</b> UNK/UNK/2012 <b>Ongoing:</b> YES
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**1.d Line/MH Number:**

Date	Location	User	Value	Reason
Sep-02-2020 12:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 12:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hypercholesterolemia	Initial Entry

**1.d Start Date:**

Date	Location	User	Value	Reason
Sep-02-2020 12:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2012	Initial Entry

**1.d Ongoing:**

Date	Location	User	Value	Reason
Sep-02-2020 12:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.e**

Date	Location	User	Value	Reason
Sep-02-2020 12:32:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number 5	Initial Entry

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951206

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

			<b>Medical History Term:</b> <b>Start Date:</b> UNK/UNK/2012 <b>Ongoing:</b> YES
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*I.e Line/MH Number:*

Date	Location	User	Value	Reason
Sep-02-2020 12:32:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 12:32:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hypertension	Initial Entry

*I.e Start Date:*

Date	Location	User	Value	Reason
Sep-02-2020 12:32:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2012	Initial Entry

*I.e Ongoing:*

Date	Location	User	Value	Reason
Sep-02-2020 12:32:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

*I.f*

Date	Location	User	Value	Reason
Sep-02-2020 12:33:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 6 <b>Medical History Term:</b> Irritable Bowel Syndrome	Initial Entry

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Header Text: c4591001

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Site No: 1095

Subject No: 10951206

Generated By: (b) (4)

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Site Name: (1095) Tekton Research

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Generated Time (GMT): 29-Mar-2021 10:39

			<b>Start Date:</b> UNK/UNK/2005	
			<b>Ongoing:</b> YES	

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

Date	Location	User	Value	Reason
Sep-02-2020 12:33:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 6	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 12:33:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Irritable Bowel Syndrome	Initial Entry

***1.f Start Date:***

Date	Location	User	Value	Reason
Sep-02-2020 12:33:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2005	Initial Entry

***1.f Ongoing:***

Date	Location	User	Value	Reason
Sep-02-2020 12:33:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***1.g***

Date	Location	User	Value	Reason
Sep-02-2020 12:33:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 7 <b>Medical History Term:</b> Seasonal Allergies <b>Start Date:</b> UNK/UNK/2010 <b>Ongoing:</b> YES	Initial Entry

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Header Text: c4591001

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Subject No: 10951206

Generated By: (b) (4)

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Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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

Date	Location	User	Value	Reason
Sep-02-2020 12:33:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 12:33:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Seasonal Allergies	Initial Entry

**I.g Start Date:**

Date	Location	User	Value	Reason
Sep-02-2020 12:33:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2010	Initial Entry

**I.g Ongoing:**

Date	Location	User	Value	Reason
Sep-02-2020 12:33:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.h**

Date	Location	User	Value	Reason
Sep-02-2020 12:34:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 8 <b>Medical History Term:</b> Cervical fusion <b>Start Date:</b> UNK/UNK/2012	Initial Entry

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Subject No: 10951206

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Site Name: (1095) Tekton Research

Subject Initials: ---

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

Date	Location	User	Value	Reason
Sep-02-2020 12:34:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 8	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 12:34:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Cervical fusion	Initial Entry

***1.h Start Date:***

Date	Location	User	Value	Reason
Sep-02-2020 12:34:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2012	Initial Entry

***1.h Ongoing:***

Date	Location	User	Value	Reason
Sep-02-2020 12:34:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2012	Initial Entry

***1.i***

Date	Location	User	Value	Reason
Sep-02-2020 12:35:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number</b> 9 :	Initial Entry

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Site No: 1095

Subject No: 10951206

Generated By: (b) (4)

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			<b>Medical History T Cyst Kidney Term:</b> <b>Start Date:</b> UNK/UNK/2015 <b>Ongoing:</b> YES
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***1.i Line/MH Number:***

Date	Location	User	Value	Reason
Sep-02-2020 12:35:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 9	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 12:35:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Cyst Kidney	Initial Entry

***1.i Start Date:***

Date	Location	User	Value	Reason
Sep-02-2020 12:35:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2015	Initial Entry

***1.i Ongoing:***

Date	Location	User	Value	Reason
Sep-02-2020 12:35:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***1.j***

Date	Location	User	Value	Reason
Sep-02-2020 12:35:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 10 <b>Medical History Term:</b> Kidney stones	Initial Entry

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Header Text: c4591001

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Site No: 1095

Subject No: 10951206

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Site Name: (1095) Tekton Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

			<b>Start Date:</b> UNK/UNK/2015 <b>Ongoing:</b> NO End Date: UNK/UNK/2015
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***I.j Line/MH Number:***

Date	Location	User	Value	Reason
Sep-02-2020 12:35:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 12:35:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Kidney stones	Initial Entry

***I.j Start Date:***

Date	Location	User	Value	Reason
Sep-02-2020 12:35:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2015	Initial Entry

***I.j Ongoing:***

Date	Location	User	Value	Reason
Sep-02-2020 12:35:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: UNK/UNK/2015	Initial Entry

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Subject No: 10951206

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<i>1.k</i>				
Date	Location	User	Value	Reason
Sep-02-2020 12:36:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 11 <b>Medical History Term:</b> Right Hip Replacement <b>Start Date:</b> UNK/UNK/2010 <b>Ongoing:</b> NO End Date: UNK/UNK/2010	Initial Entry

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Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-02-2020 12:36:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 12:36:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Right Hip Replacement	Initial Entry

**1.k Start Date:**

Date	Location	User	Value	Reason
Sep-02-2020 12:36:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2010	Initial Entry

**1.k Ongoing:**

Date	Location	User	Value	Reason
Sep-02-2020 12:36:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2010	Initial Entry

**1.l**

Date	Location	User	Value	Reason
Oct-26-2020 14:10:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Line/MH</b> 12 <b>Number:</b> <b>Medical Hi</b> Transurethral resec <b>story Term</b> tion of the prostate : <b>Start Date:</b> UNK/UNK/2017	Transcription Error

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**Header Text:** c4591001

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

			<b>Ongoing:</b> NO End Date:  UNK/UNK/2017	
Oct-26-2020 14:10:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Line/MH</b> 12 <b>Number:</b> <b>Medical Hi</b> Transurethral resec <b>story Term</b> tion of the prostate : <b>Start Date:</b> UNK/UNK/2017 <b>Ongoing:</b> NO End Date:  UNK/UNK/2019	Transcription Error
Sep-02-2020 12:37:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 12 <b>Number:</b> <b>Medical Hi</b> Transurethral resec <b>story Term</b> tion of the prostate : <b>Start Date:</b> UNK/UNK/2019 <b>Ongoing:</b> NO End Date:  UNK/UNK/2019	Initial Entry

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Generated By: (b) (4)

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Site Name: (1095) Tekton Research

Subject Initials: ---

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1.1 Line/MH Number:

Date	Location	User	Value	Reason
Sep-02-2020 12:37:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 12	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 12:37:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Transurethral resection of the pro state	Initial Entry

1.1 Start Date:

Date	Location	User	Value	Reason
Oct-26-2020 14:10:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2017	Transcription Error
Sep-02-2020 12:37:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2019	Initial Entry

1.1 Ongoing:

Date	Location	User	Value	Reason
Oct-26-2020 14:10:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2017	Transcription Error
Sep-02-2020 12:37:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2019	Initial Entry

1.m

Date	Location	User	Value	Reason
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Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

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Subject No: 10951206

Generated By: (b) (4)

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Site Name: (1095) Tekton Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

Sep-02-2020 12:38:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Num</b> 13 <b>ber:</b> <b>Medical Histor</b> Sulfa drug allerg <b>y Term:</b> y (hives) <b>Start Date:</b> UNK/UNK/198 8 <b>Ongoing:</b> YES	Initial Entry
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***1.m Line/MH Number:***

Date	Location	User	Value	Reason
Sep-02-2020 12:38:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 13	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 12:38:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sulfa drug allergy (hives)	Initial Entry

***1.m Start Date:***

Date	Location	User	Value	Reason
Sep-02-2020 12:38:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1988	Initial Entry

***1.m Ongoing:***

Date	Location	User	Value	Reason
Sep-02-2020 12:38:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***1.n***

Date	Location	User	Value	Reason
Sep-03-2020 09:20:52 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

Time (US & Canada)		(b) (4), (b) (6)	<b>Line/MH Number:</b> 14 <b>Medical History Term:</b> Spinal Cord stimulator Insertion <b>Start Date:</b> UNK/UNK/2009 <b>Ongoing:</b> YES	
Sep-02-2020 12:39:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 14 <b>Medical History Term:</b> Spinal Cord stimulator <b>Start Date:</b> UNK/UNK/2009 <b>Ongoing:</b> YES	Initial Entry

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951206

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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

Date	Location	User	Value	Reason
Sep-02-2020 12:39:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 14	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 19:00:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Sep-03-2020 09:20:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Sep-03-2020 09:20:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Spinal Cord stimulator Insertion	Changed Information
Sep-02-2020 18:03:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify SPINAL CORD STIMULATOR as follows...Device only term. Are you reporting INSERTION? REMOVAL? INFECTION OF? Other? Please clarify further and edit. Thank you.
Sep-02-2020 12:39:06 (UTC-06:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Spinal Cord stimulator	Initial Entry

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951206

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

Central Time (US & Canada)				
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***I.n Start Date:***

Date	Location	User	Value	Reason
Sep-02-2020 12:39:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2009	Initial Entry

***I.n Ongoing:***

Date	Location	User	Value	Reason
Sep-02-2020 12:39:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***I.o***

Date	Location	User	Value	Reason
Sep-24-2020 11:59:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number 15 : Medical History T right hip pain erm: Start Date: UNK/UNK/2 017 Ongoing: YES	Initial Entry

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951206

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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

Date	Location	User	Value	Reason
Sep-24-2020 11:59:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 15	Initial Entry

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

Date	Location	User	Value	Reason
Sep-24-2020 11:59:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> right hip pain	Initial Entry

**1.o Start Date:**

Date	Location	User	Value	Reason
Sep-24-2020 11:59:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2017	Initial Entry

**1.o Ongoing:**

Date	Location	User	Value	Reason
Sep-24-2020 11:59:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.p**

Date	Location	User	Value	Reason
Oct-26-2020 14:13:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 16 Medical History Term: Benign prostatic hyperplasia Start Date: UNK/UNK/2017 Ongoing: NO End Date: UNK/UNK/2017	Initial Entry

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951206

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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

Date	Location	User	Value	Reason
Oct-26-2020 14:13:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 16	Initial Entry

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

Date	Location	User	Value	Reason
Oct-26-2020 14:13:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Benign prostatic hyperplasia	Initial Entry

***1.p Start Date:***

Date	Location	User	Value	Reason
Oct-26-2020 14:13:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2017	Initial Entry

***1.p Ongoing:***

Date	Location	User	Value	Reason
Oct-26-2020 14:13:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: UNK/UNK/2017	Initial Entry

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1095

Subject No: 10951206

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Date:**

Date	Location	User	Value	Reason
Sep-02-2020 11:54:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sep/2/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Sep-02-2020 11:54:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 68.9	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Sep-02-2020 11:54:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Sep-02-2020 11:54:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 165.5	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Sep-02-2020 11:54:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> cm	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Sep-02-2020 11:54:53 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 25.2	Initial Entry

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1095

Subject No: 10951206

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

Time (US & Canada)				
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7.a

Date	Location	User	Value	Reason
Sep-02-2020 11:54:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> 1 : <b>Temperature:</b> 98.4 <b>Temperature Unit</b> F : <b>Temperature Location:</b> ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-02-2020 11:54:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-02-2020 11:54:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 98.4	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-02-2020 11:54:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-02-2020 11:54:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** RANDOMIZATION - eCRF Audit Trail History

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Sep-02-2020 12:40:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/2/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Sep-02-2020 12:40:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 249910	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951206

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-02-2020 11:55:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-02-2020 11:55:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-02-2020 19:13:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-02-2020 11:55:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-02-2020 11:55:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/2/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-02-2020 19:13:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPY2YJ	Initial Entry

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (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: 1095

Site Name: (1095) Tekton Research

Subject No: 10951206

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.a Sample ID

Date	Location	User	Value	Reason
Sep-02-2020 19:13:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPY2YJ	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-02-2020 19:13:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPY2YK	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-02-2020 19:13:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPY2YK	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-02-2020 19:13:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPY2YL	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-02-2020 19:13:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPY2YL	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-02-2020 19:13:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPCT4R	Initial Entry

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (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:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**5.d Sample ID**

Date	Location	User	Value	Reason
Sep-02-2020 19:13:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPCT4R	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951206

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-02-2020 11:55:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-02-2020 11:55:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-02-2020 19:10:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-02-2020 11:55:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-02-2020 11:55:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/2/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-02-2020 19:10:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BP3BJM	Initial Entry

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (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:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-02-2020 19:10:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP3BJM	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1095

Subject No: 10951206

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Sep-02-2020 12:41:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-02-2020 12:41:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-02-2020 12:41:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Sep-02-2020 12:41:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/2/2020 12:07	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-02-2020 12:41:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Sep-02-2020 12:41:05 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1095

Subject No: 10951206

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

Time (US & Canada)	(b) (4), (b) (6)
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7. Route:

Date	Location	User	Value	Reason
Sep-02-2020 12:41:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-02-2020 12:41:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 12:41:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Sep-02-2020 11:55:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGENICITY E-DI ARY NOT COLLECTED FOR T HIS SUBJECT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1095

**Subject No:** 10951206

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

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

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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*1. Date of Visit*

Date	Location	User	Value	Reason
Sep-24-2020 10:54:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/24/2020	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 15-Sep-2020 21:54

Site No: 1095

Subject No: 10951206

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Date:**

Date	Location	User	Value	Reason
Sep-24-2020 11:23:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/24/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-24-2020 11:23:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> 1 : <b>Temperature:</b> 98.5 <b>Temperature Unit</b> F : <b>Temperature Location:</b> ORAL CAV <b>ity:</b> ITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-24-2020 11:23:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Sep-24-2020 11:23:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 98.5	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Sep-24-2020 11:23:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 15-Sep-2020 21:54

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

**2.a Temperature Location:**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-24-2020 11:23:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1095**Subject No:** 10951206**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1095) Tekton Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-24-2020 11:23:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-24-2020 11:23:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-24-2020 14:19:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-24-2020 11:23:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-24-2020 11:23:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/24/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-24-2020 14:19:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BP1N3W	Initial Entry



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-24-2020 14:19:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP1N3W	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1095

Subject No: 10951206

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Sep-24-2020 10:55:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-24-2020 10:55:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-24-2020 10:55:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Sep-24-2020 10:55:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/24/2020 10:45	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-24-2020 10:55:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Sep-24-2020 10:55:17 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1095

Subject No: 10951206

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

Time (US & Canada)	(b) (4), (b) (6)
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7. Route:

Date	Location	User	Value	Reason
Sep-24-2020 10:55:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-24-2020 10:55:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-24-2020 10:55:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951206

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

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

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-23-2020 11:06:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/23/2020	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: 1095

Site Name: (1095) Tekton Research

Subject No: 10951206

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-23-2020 11:07:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-23-2020 11:07:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-25-2020 10:26:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-24-2020 03:31:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-23-2020 11:07:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-23-2020 11:07:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/23/2020	Initial Entry

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (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: 1095

Site Name: (1095) Tekton Research

Subject No: 10951206

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.a

Date	Location	User	Value	Reason
Oct-25-2020 10:26:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BRDFZM</b>	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-25-2020 10:26:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRDFZM	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-25-2020 10:27:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BRDFZN</b>	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-25-2020 10:27:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRDFZN	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-25-2020 10:27:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BRDFZP</b>	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-25-2020 10:27:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRDFZP	Initial Entry

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (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: 1095

Site Name: (1095) Tekton Research

Subject No: 10951206

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.d

Date	Location	User	Value	Reason
Oct-25-2020 10:41:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BPLJW1</b>	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Oct-25-2020 10:41:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPLJW1	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-25-2020 10:42:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BPLJW0</b>	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Oct-25-2020 10:42:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPLJW0	Initial Entry

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

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

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

**Site No:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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

Date	Location	User	Value	Reason
Oct-23-2020 11:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/23/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-23-2020 11:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-23-2020 11:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)



Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Incomplete, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951206

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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

Date	Location	User	Value	Reason
Mar-10-2021 13:15:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Mar-03-2021 09:32:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/26/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Mar-10-2021 13:15:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Mar-03-2021 09:32:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Mar-10-2021 16:45:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Closed	Response satisfies query
Mar-10-2021 13:15:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query
Mar-10-2021 11:41:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Reissued:Opened	CLINQUERY: Thank you, please clear entire page if entry was in error and subject remains on study (date field remains)
Mar-10-2021 07:59:57 (UTC-06:00) Central	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form:** DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

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

**Form Status:** Incomplete, Verified

**Site No:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

Time (US & Canada)				
Mar-10-2021 07:59:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Mar-10-2021 00:25:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINQUERY: Disp FUP (end of study) is marked as COMPLETED but subject has not finished all follow up on the trial. Please review entry - if subject has ceased participation in trial, please select a Status to match reason for end of study
Mar-09-2021 13:27:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Candidate	CLINQUERY: Disp FUP (end of study) is marked as COMPLETED but subject has not finished all follow up on the trial. Please review entry - if subject has ceased participation in trial, please select a Status to match reason for end of study
Mar-04-2021 22:49:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-04-2021 11:27:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Mar-04-2021 11:27:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

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**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

**Form Status:** Incomplete, Verified

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

Mar-04-2021 00:05:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Please verify, if subject is ongoing in the study or completed study. If ongoing, then remove details on this form if not then update status accordingly or else clarify. Thank you.
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090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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Date	Location	User	Value	Reason
Sep-24-2020 11:28:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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Date	Location	User	Value	Reason
Jan-26-2021 17:13:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1095

Subject No: 10951206

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Category:**

Date	Location	User	Value	Reason
Sep-24-2020 11:28:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Sep-24-2020 11:28:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Sep-24-2020 11:28:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> osteoporosis right hip	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Sep-24-2020 11:28:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/22/2020 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Mar-05-2021 10:00:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Nov/15/2020 UNK:UNK	New Information
Mar-05-2021 09:55:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query

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Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1095

Subject No: 10951206

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

Mar-05-2021 09:55:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Nov/12/2020 UNK:UNK	New Information
Mar-03-2021 09:32:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please review and update as appropriate.
Sep-24-2020 11:28:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Sep-24-2020 11:28:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

Date	Location	User	Value	Reason
Jan-27-2021 14:36:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	SAE term has been added; will query there
Jan-27-2021 14:33:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-27-2021 09:47:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kate Jurek (b) (4)	Query 2: Answered	Done.

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Jan-26-2021 17:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	This has been updated
Jan-12-2021 08:46:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical On review of SAE report for ruptured blood vessel, an event of Rt THR[on 12Nov20] was mentioned, yet it does not appear on the AE CRF; please update AE log. If a SAE, submit the event as a followup SAE (#2021015538) safety update by FAX
Jan-12-2021 08:41:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL Please enter SAE (#2021015538) of Ruptured Blood Vessel on AE CRF.
Sep-24-2020 11:28:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Sep-24-2020 11:28:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Sep-24-2020 11:28:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:	Initial Entry

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			OTHER  If Other, specify:  wear/aging	
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-24-2020 11:28:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-24-2020 11:28:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-27-2021 14:34:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-27-2021 09:49:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kate Jurek (b) (4)	Query 1: Answered	Hip replacement was scheduled in June of 2020 due to received lab results. Not SAE. Pt. did have increasing hip pain, however procedure completed was based on lab work, not pain.
Jan-13-2021 16:41:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL Event of Rt hip OA has non-drug treatment = No; if Rt THR was performed on 12Nov20 for OA of

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				hip, please review and update non-drug treatment as appropriate
Sep-24-2020 11:28:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Mar-05-2021 10:01:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-05-2021 10:01:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	New Information
Mar-05-2021 09:55:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE osteoporosis right hip: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Sep-24-2020 11:28:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-24-2020 11:28:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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Generated By: (b) (4)

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**1. Category:**

Date	Location	User	Value	Reason
Jan-26-2021 17:13:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Jan-26-2021 17:13:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Feb-25-2021 14:13:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Feb-25-2021 14:12:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Feb-25-2021 14:12:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-09-2021 08:35:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Date has been corrected, updated and resubmitted.
Feb-09-2021 08:35:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Update has been submitted. Medications unknown as medical records have not been received.
Feb-09-2021 08:34:46 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	This has been updated and resubmitted.

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

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Time (US & Canada)		(b) (4), (b) (6)		
Feb-08-2021 19:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	Clinical - SAE report states THR discharge med is amoxicillin (thank you); please submit medications administered during the hospitalization/surgery with a focus on anti-platelet/anti-coagulant drugs
Feb-08-2021 19:12:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Clinical Thank you. For hip surgery date, current SAE report has 'Rt hip replacement on 12Nov20' and also 'subject reported to surgery center for planned Rt hip replacement on 15Nov2020'. Please clarify date & update in one location
Feb-08-2021 19:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Clinical The SAE event term is Ruptured Blood Vessel behind Lt eye; however, SAE report term is Ruptured Blood Vessel. Please submit a SAE safety followup to update the event term location (Lt eye)
Feb-04-2021 11:28:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-04-2021 09:54:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	updated as requested

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Subject Initials: ---

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Feb-04-2021 09:54:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ruptured blood vessel behind Left eye	updated as requested
Feb-04-2021 09:53:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	SAE has been updated
Jan-30-2021 20:09:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical - Please update the event term with the location of the ruptured blood vessel, in both AE CRF and SAE update
Jan-27-2021 14:47:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical Start date of bleeding vessel is 14Nov20 and subject underwent Rt THR on 12Nov20, per Med Hx, presumably Hospitalized. Please submit this event including the operative/post- operative meds received esp relevant to anti-coagulation, to SAE report
Jan-26-2021 17:13:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ruptured blood vessel	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-08-2021 19:05:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	start date is 17Nov20 in both locations now
Feb-08-2021 13:07:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Updated SAE was submitted on 04 FEB 2021. This was both faxed and emailed. The corrected date 17 NOV 2020

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Subject Initials: ---

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Feb-05-2021 11:31:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2021015538 ,the Onset Date was reported as 14-NOV-2020 in Safety database but in InFORM the Start date 17/Nov/2020. Dates are to match therefore please update INFORM or submit a follow-up safety report to update Safety.
Jan-28-2021 12:08:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kate Jurek (b) (4)	<b>Data Entry:</b> Nov/17/2020 UNK:UNK	Incorrect date reported.
Jan-26-2021 17:13:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/14/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-28-2021 12:08:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-28-2021 12:08:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kate Jurek (b) (4)	<b>Data Entry:</b> NO End Date Time:  Nov/18/2020 UNK:UNK	Incorrect date reported.
Jan-28-2021 12:08:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For ruptured blood vessel End Date & Time 15/Nov/2020 UNK:UNK is before the Start Date & Time 17/Nov/2020 UNK:UNK.
Jan-26-2021 17:13:54 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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Time (US & Canada)		(b) (4), (b) (6)	End Date Time:	
			Nov/15/2020 UNK:UNK	

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-26-2021 17:13:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-08-2021 19:02:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-08-2021 16:04:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (4), (b) (6)	Query 2: Answered	This was updated and sent on 04 FEB 2021
Jan-28-2021 06:42:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-27-2021 14:40:01 (UTC-06:00) Central 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 [#2021015538] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results.

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Jan-26-2021 17:13:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE ruptured blood vessel: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-26-2021 17:13:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b> YES</p> <p>Is this serious event associate d with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result i n death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result i n persistent or significant disa bility/incapacity?</p> <p>NO</p> <p>Is this serious event life threat ening?</p> <p>NO</p> <p>Other medically important ser ious event</p> <p>NO</p>	Initial Entry

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

Date	Location	User	Value	Reason
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Jan-26-2021 17:13:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-26-2021 17:13:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  If Other, specify:  epistaxis	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-26-2021 17:13:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-26-2021 17:13:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-26-2021 17:13:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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**Form Status:** Data Complete, Frozen

**Site No:** 1095

**Site Name:** (1095) Tekton Research

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**Subject Initials:** ---

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

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Jan-26-2021 17:13:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry
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**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Jan-26-2021 17:13:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Jan-28-2021 06:42:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2021015538	Initial Entry

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**Header Text:** c4591001

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

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

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Jan-08-2021 18:16:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kate Jurek (b) (4)	<b>Data Entry:</b> Jan/7/2021	Initial Entry

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit  
Trail History

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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

Date	Location	User	Value	Reason
Jan-08-2021 18:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kate Jurek (b) (4)	<b>Data Entry:</b> Participant is willing to return for Vaccination 3 Participant is:  eligible per local/national reco mmendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1095

**Subject No:** 10951206

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

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

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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*1. Date of Visit*

Date	Location	User	Value	Reason
Jan-08-2021 18:16:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kate Jurek (b) (4)	<b>Data Entry:</b> Jan/8/2021	Initial Entry

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1095

**Subject No:** 10951206

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

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

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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*I. Consent Was:*

Date	Location	User	Value	Reason
Jan-08-2021 18:17:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kate Jurek (b) (4)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Jan/8/2021	Initial Entry

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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

Date	Location	User	Value	Reason
Jan-11-2021 17:36:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/8/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Jan-11-2021 17:36:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> REPEAT SCREENING 1	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Jan-11-2021 17:36:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (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:** 1095**Site Name:** (1095) Tekton Research**Subject No:** 10951206**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-11-2021 17:37:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-11-2021 17:37:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-11-2021 17:37:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-11-2021 17:37:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-11-2021 17:37:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/8/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-11-2021 17:37:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BP1T9T	Initial Entry



Header Text: c4591001

Visit: V101\_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951206

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.a Sample ID

Date	Location	User	Value	Reason
Jan-11-2021 17:37:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP1T9T	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-11-2021 17:37:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP1T9V	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-11-2021 17:37:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP1T9V	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-11-2021 17:37:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP1T9W	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-11-2021 17:37:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP1T9W	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-11-2021 18:08:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPCTGC	Initial Entry

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (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:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**5.d Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Jan-11-2021 18:08:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPCTGC	Initial Entry

**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:** 1095**Site Name:** (1095) Tekton Research**Subject No:** 10951206**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-11-2021 17:36:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-11-2021 17:36:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-11-2021 17:36:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-11-2021 17:36:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-11-2021 17:36:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/8/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-11-2021 17:36:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BP1NCN	Initial Entry

**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:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-11-2021 17:36:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP1NCN	Initial Entry

Header Text: c4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1095

Subject No: 10951206

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Jan-12-2021 10:09:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Jan-12-2021 10:09:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Jan-12-2021 10:09:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Jan-13-2021 11:49:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-13-2021 11:40:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-13-2021 11:40:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/8/2021 15:11	Transcription Error
Jan-12-2021 15:22:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Per source, the time is '15:11'. Please verify and update, thanks
Jan-12-2021 10:09:38	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (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: 1095

Site Name: (1095) Tekton Research

Subject No: 10951206

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	Jan/8/2021 14:11	
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**5. Anatomical Location:**

Date	Location	User	Value	Reason
Jan-12-2021 10:09:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Jan-12-2021 10:09:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Jan-12-2021 10:09:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

**8. Actual Dose:**

Date	Location	User	Value	Reason
Jan-12-2021 10:09:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

**9. Unit:**

Date	Location	User	Value	Reason
Jan-12-2021 10:09:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Jan-12-2021 10:09:38	ACV0PFEINFP6000	auto calc	<u>Data Entry:</u>	Initial Entry

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (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:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

(UTC-06:00) Central Time (US & Canada)		(autocalc)	30 MINUTES	
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**II. Was the subject observed for at least the protocol specified observation period after investigational product administration?**

Date	Location	User	Value	Reason
Jan-12-2021 10:09:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Jan-08-2021 18:14:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kate Jurek (b) (4)	<b>Data Entry:</b> Jan/7/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Jan-08-2021 18:14:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kate Jurek (b) (4)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)



**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** WITHDRAWAL OF CONSENT - eCRF Audit Trail History

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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***1. Withdrawal of Consent Date :***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Jan-08-2021 18:15:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kate Jurek (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** DEATH DETAILS CODED - eCRF Audit Trail History

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Jan-08-2021 18:15:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kate Jurek (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1095

**Subject No:** 10951206

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

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

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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*1. Date of Visit*

Date	Location	User	Value	Reason
Jan-28-2021 13:13:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kate Jurek (b) (4)	<b>Data Entry:</b> Jan/28/2021	Initial Entry

Header Text: c4591001

Visit: V102\_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951206

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-28-2021 13:14:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-28-2021 13:14:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-29-2021 13:11:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-29-2021 02:33:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-28-2021 13:14:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-28-2021 13:14:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kate Jurek (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Jan/28/2021	Initial Entry

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (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:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**5.a**

Date	Location	User	Value	Reason
Jan-29-2021 13:11:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BR0VDK	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-29-2021 13:11:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR0VDK	Initial Entry

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)

Header Text: c4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1095

Subject No: 10951206

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Jan-28-2021 13:32:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kate Jurek (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Jan-28-2021 13:32:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Jan-28-2021 13:32:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Jan-28-2021 13:32:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kate Jurek (pfe.kjurek)	<b>Data Entry:</b> Jan/28/2021 13:14	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Jan-28-2021 13:32:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Jan-28-2021 13:32:38 (UTC-06:00) Central	ACV0PFEINFP6000	Kate Jurek (b) (4)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)

Header Text: c4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1095

Subject No: 10951206

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

Time (US & Canada)				
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**7. Route:**

Date	Location	User	Value	Reason
Jan-28-2021 13:32:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

**8. Actual Dose:**

Date	Location	User	Value	Reason
Jan-28-2021 13:32:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

**9. Unit:**

Date	Location	User	Value	Reason
Jan-28-2021 13:32:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Jan-28-2021 13:32:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-28-2021 13:32:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kate Jurek (b) (4)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1095

**Subject No:** 10951206

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

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

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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*I. Date of Visit*

Date	Location	User	Value	Reason
Mar-03-2021 09:39:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-02-2021 18:10:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	This has been updated
Mar-01-2021 04:52:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	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 visit at visit 103.
Feb-26-2021 09:41:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/26/2021	Initial Entry

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)



**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1095

**Subject No:** 10951206

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

**Form:** CONTACT OUTCOME - eCRF Audit Trail History

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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**1. Contact Type:**

Date	Location	User	Value	Reason
Feb-26-2021 09:41:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Feb-26-2021 09:41:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Contact:  Feb/26/2021	Initial Entry

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (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:** 1095**Site Name:** (1095) Tekton Research**Subject No:** 10951206**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Mar-03-2021 15:24:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Response satisfies query
Mar-03-2021 09:32:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: An swere d	Changed data per query
Mar-03-2021 04:30:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW7582528;Status on the Disposition - Treatment form is COMPLETED, but Date is different than Visit 3 Date. Please review and update as appropriate.
Mar-02-2021 18:09:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : Feb/2 6/202 1	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Mar-02-2021 18:09:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> OPEN LABEL TREATMENT	Initial Entry

**3. Status:**

**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:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Mar-02-2021 18:09:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

**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:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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**1. Subject Status**

Date	Location	User	Value	Reason
Mar-10-2021 07:59:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Transcription Error
Mar-04-2021 11:27:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COMPLETED	Initial Entry
Oct-23-2020 11:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Sep-02-2020 12:40:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Sep-02-2020 11:53:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Mar-10-2021 13:15:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/23/2020	Transcription Error
Mar-10-2021 07:59:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/23/2020	Transcription Error
Mar-04-2021 11:27:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Feb/26/2021	Initial Entry
Mar-03-2021 09:32:24 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/23/2020	Initial Entry

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (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:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

Time (US & Canada)				
Feb-11-2021 13:02:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-04-2021 10:50:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	This has been updated
Jan-11-2021 06:15:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2021015538 ruptured blood vessel(onset date:14Jan2021)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Oct-23-2020 11:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/23/2020	Initial Entry
Sep-02-2020 12:40:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/2/2020	Initial Entry
Sep-02-2020 11:53:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/2/2020	Initial Entry

090177e196ae2fb7\Final\Final On: 01-Apr-2021 03:49 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

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

**Form Status:** Data Complete, Verified

**Site No:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951206

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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*I. Casebook Signature*

Date	Location	User	Value	Reason
Nov-06-2020 14:20:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry