

**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:** 10951101

**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:** 10951101

**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 Aug/7/2020
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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:** 10951101

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[10951101]
2.	Birth Date:	(b) (6) 1954
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951101

**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	Aug/7/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951101

**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 _____
----	---	-------------------------

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951101

**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	Aug/7/2020
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: 10951101

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:	[torn right ankle tendon]
	Start Date:	UNK/UNK/2017
	Ongoing:	NO End Date: UNK/UNK/2017
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[ankel surgery (right ankle)]
	Start Date:	UNK/UNK/2017
	Ongoing:	NO End Date: UNK/UNK/2017
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[cataracts (bilateral)]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[jaw surgery- fix misalignment]
	Start Date:	UNK/UNK/2000
	Ongoing:	NO End Date: UNK/UNK/2000

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951101

**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:	[congenital jaw misalignment]
	Start Date:	(b) (6) 1954
	Ongoing:	NO End Date: UNK/UNK/2000
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[partial knee replacement (left)]
	Start Date:	UNK/UNK/2011
	Ongoing:	NO End Date: UNK/UNK/2011
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[partial knee replacement (right)]
	Start Date:	UNK/UNK/2013
	Ongoing:	NO End Date: UNK/UNK/2013
1 h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[cartilage deterioration (both knees)]
	Start Date:	UNK/UNK/2011
	Ongoing:	NO End Date: UNK/UNK/2013

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951101

**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.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[migraines]
	Start Date:	UNK/UNK/1985
	Ongoing:	YES
1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[mitral valve prolapse]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[seasonal allergies]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[tonsillitis]
	Start Date:	UNK/UNK/1965
	Ongoing:	NO End Date: UNK/UNK/1965
1.m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[tonsillectomy]
	Start Date:	UNK/UNK/1965
	Ongoing:	NO End Date: UNK/UNK/1965

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951101

**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:	[postmenopausal symptoms]
	Start Date:	UNK/UNK/2009
	Ongoing:	YES
1.o	Line/MH Number:	[15]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hepatitis B]
	Start Date:	UNK/UNK/1981
	Ongoing:	NO End Date: UNK/UNK/1981

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951101

**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:	Aug/7/2020
2.	Weight:	[99.3]
3.	Unit:	kg
4.	Height:	[173.5]
5.	Unit:	cm
6.	Body Mass Index:	[33.0]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[98.6]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951101

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

**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](#)

**Lab Urinalysis**

1.	Lab Panel:		
2.	Lab Sub-Panel:		
3.	Collection Date:	Not Applicable //	<a href="#">Comments</a>
4.	Laboratory Name and Address (Derived)	[ ]	
5.	Specimen Type:		

**Lab Result**

6.a	Sponsor ID:	[113]	
	Test:	Choriogonadotropin Beta_PX113	
	Result:	Not Applicable	<a href="#">Comments</a>
	Not Done:	NOT DONE	

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951101

**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 :	Aug/7/2020
2.	Randomization Number:	[224159]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951101

**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: Aug/7/2020
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	[BP3B XK]
5.b	Sample ID	[BP3B XL]
5.c	Sample ID	[BP3B XM]
5.d	Sample ID	[BPLJ JD]
5.e	Sample ID	[BPLJ JF]

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951101

**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: Aug/7/2020
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	[BP3BB3]
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090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951101

**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:	Aug/7/2020 15:10
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

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951101

**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	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1095

**Subject No:** 10951101

**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	Aug/28/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? NO Stop Date: Aug/13/2020

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1095

**Subject No:** 10951101

**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:	Aug/28/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[98.1]
	Unit:	F
	Temperature Location:	ORAL CAVITY

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1095

**Subject No:** 10951101

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

**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](#)

**Lab Urinalysis**

1.	Lab Panel:		
2.	Lab Sub-Panel:		
3.	Collection Date:	Not Applicable //	<a href="#">Comments</a>
4.	Laboratory Name and Address (Derived)	[ ]	
5.	Specimen Type:		

**Lab Result**

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

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1095

**Subject No:** 10951101

**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: Aug/28/2020
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	[BP3BGL]
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090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1095

**Subject No:** 10951101

**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:	Aug/28/2020 09:53
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

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951101

**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/28/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

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

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951101

**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/28/2020
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	[BPY2LW]
5.b	Sample ID	[BPY2LX]
5.c	Sample ID	[BPY2LY]
5.d	Sample ID	[BPCTC0]
5.e	Sample ID	[BPCTC1]

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1095

**Subject No:** 10951101

**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	Mar/8/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1095

**Subject No:** 10951101

**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: Mar/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	[BRBTNN]
5.b	Sample ID	[BRBTNP]
5.c	Sample ID	[BRBTNR]
5.d	Sample ID	[BPCTMY]

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1095

**Subject No:** 10951101

**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:** V5\_MONTH12\_L

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

**Site No:** 1095

**Subject No:** 10951101

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

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

**Subject Initials:** ---

**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:** V6\_MONTH24\_L

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

**Site No:** 1095

**Subject No:** 10951101

**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:** V6\_MONTH24\_L

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

**Site No:** 1095

**Subject No:** 10951101

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

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

**Subject Initials:** ---

**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:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET  
on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**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	Nov/5/2020
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	COVID_A
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19  
on Nov/05/2020

**Form Version:** 10-Oct-2020 16:02

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Signs and Symptoms**

1.	Date of Assessment:	Nov/5/2020
2.	Date of First Symptom Started:	Oct/30/2020
3.	Symptoms Ongoing?	NO
	Date of Last Symptom Resolved:	Nov/7/2020

**Symptoms**

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

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19  
on Nov/05/2020

**Form Version:** 10-Oct-2020 16:02

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

**Symptoms - Other**

5.	Symptoms - Other Text:	[ ]
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** MICROBIOLOGY SPECIMEN

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Nov/3/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** MICROBIOLOGY SPECIMEN  
on Nov/05/2020

**Form Version:** 06-Jul-2020 21:54

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[Back to Form](#)  
[eCRF Audit Trail History](#)  
[Form Audit Trail](#)

**Microbiology Specimen**

1.	Actual Date of Collection:	Nov/3/2020
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	OTHER
7.	Test Result:	NEGATIVE
8.	Comments/Findings/Details:	[ ]
9.	Trade Name Other, Specify:	[NALT unknown]

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Nov/16/2020
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	[CV17734]
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090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

**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?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[subject instructed to collect home self swab however subject states COVID testing completed in hospital]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION  
on Nov/05/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1095**Site Name:** (1095) Tekton Research**Subject No:** 10951101**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[eCRF Audit Trail History](#)**Health Care Utilization**

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

**Health Care Utilization Other**

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

**Health Care Utilization**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** HOSPITALIZATION DETAILS

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing	Form Instance
1.	HOSPITALIZATION STATUS	HOSPITAL	Nov/5/2020	NO Discharge Date:  Nov/7/2020	<a href="#">Repeating Pages</a>

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** HOSPITALIZATION DETAILS  
on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[Back to Form](#)  
[eCRF Audit Trail History](#)  
[Form Audit Trail](#)

**Hospitalization Details**

1.	Hospitalization Category:	HOSPITALIZATION STATUS
2.	Hospitalization Term:	HOSPITAL
3.	Admission Date:	Nov/5/2020
4.	Ongoing?	NO Discharge Date: Nov/7/2020

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** RESPIRATORY TREATMENT

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** RESPIRATORY TREATMENT  
on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**Respiratory Treatment**

1.	What is the treatment Identifier?	Not Applicable _____ [ ]	<a href="#">Comments</a>
2.	Concomitant Non-drug Treatment Pre-specified:	Not Applicable _____	<a href="#">Comments</a>
3.	Treatment:	Not Applicable _____	<a href="#">Comments</a>
4.	Treatment:	Not Applicable _____ [ ]	<a href="#">Comments</a>
5.	Start Date:	Not Applicable _____ //	<a href="#">Comments</a>
6.	Ongoing?	Not Applicable _____	<a href="#">Comments</a>

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS  
on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Illness Details**

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	YES Respiratory Illness Diagnosis: [Pulmonary embolism]  Date of Diagnosis: Nov/5/2020
3.	Toxicity Grade:	3

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** ILLNESS DETAILS - SEVERE

**Form Version:** 17-Jul-2020 21:55

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

#	Category of Clinical Event	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE  
on Nov/05/2020

**Form Version:** 17-Jul-2020 21:55

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**Illness Details**

1.	Category of Clinical Event:	Not Applicable _____	<a href="#">Comments</a>
2.	Subcategory of Clinical Event:	Not Applicable _____	<a href="#">Comments</a>
3.	Was a diagnosis obtained?	Not Applicable _____	<a href="#">Comments</a>
4.	Toxicity Grade:	Not Applicable _____	<a href="#">Comments</a>

Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 30-Jul-2020 21:27

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Unknown	Unknown	Unknown	Unknown	<b>Sponsor-Defined Identifier</b>	<b>Test:</b>	<b>Result:</b>	<a href="#">Repeating Pages</a>
					Unknown	Unkno wn	Unkno wn	
					Unknown	Unkno wn	Unkno wn	
					Unknown	Unkno wn	Unkno wn	
					Unknown	Unkno wn	Unkno wn	
					Unknown	Unkno wn	Unkno wn	
					Unknown	Unkno wn	Unkno wn	
					Unknown	Unkno wn	Unkno wn	

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

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

**Lab Chemistry Details**

1.	Lab Panel:	Unknown _____	<a href="#">Comments</a>
2.	Laboratory Name and Address	Unknown _____ [ ]	<a href="#">Comments</a>
3.	Collection Date:	Unknown _____ //	<a href="#">Comments</a>
4.	Specimen Type:	Unknown _____	<a href="#">Comments</a>

**Lab Result**

5.a	Sponsor ID:	Unknown _____ [ ]	<a href="#">Comments</a>
	Test:	C Reactive Protein_PX329	
	Result:	Unknown _____ [ ]	<a href="#">Comments</a>
	Not Done:	Unknown _____	<a href="#">Comments</a>
	LNMT	Unknown _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

5.b	Sponsor ID:	Unknown _____	<a href="#">Comments</a>
		[ ]	
	Test:	Alanine Aminotransferase_PX30	
	Result:	Unknown _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Unknown _____	<a href="#">Comments</a>	
LNMT	Unknown _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

5.c	Sponsor ID:	Unknown _____	<a href="#">Comments</a>
		[ ]	
	Test:	Aspartate Aminotransferase_PX28	
	Result:	Unknown _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Unknown _____	<a href="#">Comments</a>	
LNMT	Unknown _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

5.d	Sponsor ID:	Unknown _____	<a href="#">Comments</a>
		[ ]	
	Test:	Alkaline Phosphatase_PX35	
	Result:	Unknown _____	<a href="#">Comments</a>
		[ ]	
	Not Done:	Unknown _____	<a href="#">Comments</a>
	LNMT	Unknown _____	<a href="#">Comments</a>
		Low [ ] High [ ] Unit	

5.e	Sponsor ID:	Unknown _____	<a href="#">Comments</a>
		[ ]	
	Test:	Bilirubin_PX21	
	Result:	Unknown _____	<a href="#">Comments</a>
		[ ]	
	Not Done:	Unknown _____	<a href="#">Comments</a>
	LNMT	Unknown _____	<a href="#">Comments</a>
		Low [ ] High [ ] Unit	

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

5.f	Sponsor ID:	Unknown _____	<a href="#">Comments</a>
		[ ]	
	Test:	Blood Urea Nitrogen_PX47	
	Result:	Unknown _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Unknown _____	<a href="#">Comments</a>	
LNMT	Unknown _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

5.g	Sponsor ID:	Unknown _____	<a href="#">Comments</a>
		[ ]	
	Test:	Creatinine_PX48	
	Result:	Unknown _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Unknown _____	<a href="#">Comments</a>	
LNMT	Unknown _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 30-Jul-2020 21:28

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Unknown	Unknown	Unknown	Unknown	<b>Sponsor-Defined Identifier</b>	<b>Test:</b>	<b>Result :</b>	<a href="#">Repeating Pages</a>
					Unknown	Unkno wn	Unkno wn	
					Unknown	Unkno wn	Unkno wn	
					Unknown	Unkno wn	Unkno wn	
					Unknown	Unkno wn	Unkno wn	
					Unknown	Unkno wn	Unkno wn	
					Unknown	Unkno wn	Unkno wn	
					Unknown	Unkno wn	Unkno wn	
					Unknown	Unkno wn	Unkno wn	
					Unknown	Unkno wn	Unkno wn	
					Unknown	Unkno wn	Unkno wn	

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology on Nov/05/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

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

**Laboratory Data Hematology**

1.	Lab Panel:	Unknown _____	<a href="#">Comments</a>
2.	Laboratory Name and Address	Unknown _____ [ ]	<a href="#">Comments</a>
3.	Collection Date:	Unknown _____ //	<a href="#">Comments</a>
4.	Specimen Type:	Unknown _____	<a href="#">Comments</a>

**Lab Result**

5.a	Sponsor ID:	Unknown _____ [ ]	<a href="#">Comments</a>
	Test:	Hemoglobin_PX1	
	Result:	Unknown _____ [ ]	<a href="#">Comments</a>
	Not Done:	Unknown _____	<a href="#">Comments</a>
	LNMT	Unknown _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

5.b	Sponsor ID:	Unknown _____	<a href="#">Comments</a>
		[ ]	
	Test:	Hematocrit_PX2	
	Result:	Unknown _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Unknown _____	<a href="#">Comments</a>	
LNMT	Unknown _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

5.c	Sponsor ID:	Unknown _____	<a href="#">Comments</a>
		[ ]	
	Test:	Erythrocytes_PX3	
	Result:	Unknown _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Unknown _____	<a href="#">Comments</a>	
LNMT	Unknown _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

5.d	Sponsor ID:	Unknown _____	<a href="#">Comments</a>
		[ ]	
	Test:	Platelets_PX5	
	Result:	Unknown _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Unknown _____	<a href="#">Comments</a>	
LNMT	Unknown _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

5.e	Sponsor ID:	Unknown _____	<a href="#">Comments</a>
		[ ]	
	Test:	Leukocytes_PX7	
	Result:	Unknown _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Unknown _____	<a href="#">Comments</a>	
LNMT	Unknown _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

5.f	Sponsor ID:	Unknown _____	<a href="#">Comments</a>
		[ ]	
	Test:	Neutrophils_PX608	
	Result:	Unknown _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Unknown _____	<a href="#">Comments</a>	
LNMT	Unknown _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

5.g	Sponsor ID:	Unknown _____	<a href="#">Comments</a>
		[ ]	
	Test:	Eosinophils_PX609	
	Result:	Unknown _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Unknown _____	<a href="#">Comments</a>	
LNMT	Unknown _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

5.h	Sponsor ID:	Unknown _____	<a href="#">Comments</a>
		[ ]	
	Test:	Monocytes_PX612	
	Result:	Unknown _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Unknown _____	<a href="#">Comments</a>	
LNMT	Unknown _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

5.i	Sponsor ID:	Unknown _____	<a href="#">Comments</a>
		[ ]	
	Test:	Basophils_PX610	
	Result:	Unknown _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Unknown _____	<a href="#">Comments</a>	
LNMT	Unknown _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

5.j	Sponsor ID:	Unknown _____ [ ]	<a href="#">Comments</a>
	Test:	Lymphocytes_PX611	
	Result:	Unknown _____ [ ]	<a href="#">Comments</a>
	Not Done:	Unknown _____	<a href="#">Comments</a>
	LNMT	Unknown _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** VITAL SIGNS - COVID

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

#	Date:	Vital Signs Details			Form Instance
1.	Unknown	<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>
		Not Done	Unknown	Unknown	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** VITAL SIGNS - COVID  
on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

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

**Vital Signs**

1.	Date:	Unknown _____ //	<a href="#">Comments</a>
----	-------	------------------------	--------------------------

**Vital Signs Details**

2.a	Record Identifier:	Unknown _____ 1	
	Systolic:	Unknown _____ [ ]	<a href="#">Comments</a>
	Diastolic:	Unknown _____ [ ]	<a href="#">Comments</a>
	Respiratory Rate in respirations/minute:	Unknown _____ [ ]	<a href="#">Comments</a>
	Heart Rate in beats/minute:	Unknown _____ [ ]	<a href="#">Comments</a>

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** VITAL SIGNS - PULSE OX ROOM AIR

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

#	Date:	Vital Signs Details		Form Instance
1.	Unknown	<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>
		Unknown	Unknown	



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** VITAL SIGNS - PULSE OX ROOM AIR  
on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

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

**Vital Signs**

1.	Date:	Unknown _____ //	<a href="#">Comments</a>
----	-------	------------------------	--------------------------

**Vital Signs Details**

2.a	Record Identifier:	Unknown _____ 1	
	SPO2 Pulse Oximetry %	Unknown _____ [ ]	<a href="#">Comments</a>

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** OXYGENATION PARAMETERS

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.	Unknown	Unknown	Unknown	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS  
on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**Oxygenation Parameters**

1.	Date Time of Assessment:	Unknown _____ //	<a href="#">Comments</a>
2.	Arterial Blood Gases PaO2 (mmHg):	Unknown _____ [ ]	<a href="#">Comments</a>
3.	FiO2 (Fraction of Inhaled Oxygen):	Unknown _____ [ ]	<a href="#">Comments</a>

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

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

**Site No:** 1095

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

**Subject No:** 10951101

**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.	Unknown	Unknown	Unknown	Unknown	Unknown	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS  
on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**Concomitant Medications**

1.	What is the medication identifier?	Unknown _____ [ ]	<a href="#">Comments</a>
2.	Category:	Unknown _____	<a href="#">Comments</a>
3.	Concomitant Medications Pre-specified:	Unknown _____	<a href="#">Comments</a>
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).	Unknown _____ [ ]	<a href="#">Comments</a>
5.	Start Date:	Unknown _____ //	<a href="#">Comments</a>
6.	Ongoing?	Unknown _____	<a href="#">Comments</a>

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** IMAGING

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Nov/5/2020	CHEST	X-RAY	UNKNOWN	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** IMAGING  
on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[Back to Form](#)  
[eCRF Audit Trail History](#)  
[Form Audit Trail](#)

**Imaging**

1.	Date of Assessment:	Nov/5/2020
2.	Location of Assessment:	CHEST
3.	Type of Imaging Exam:	X-RAY
4.	Assessment:	UNKNOWN

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1095

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

**Subject No:** 10951101

**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:	
----	-------------------------	--



**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:** 10951101

**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:** 10951101

**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:** 10951101

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

**Site No:** 1095

**Subject No:** 10951101

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

**Form:** DISPOSITION - TREATMENT

**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 - Treatment**

1.	Date of Completion/Discontinuation /Death :	Sep/28/2020
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:** 10951101

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

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**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:** 10951101

**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:	
----	-----------------------	--

**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:** 10951101

**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:** 10951101

**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	Pulmonary Embolism	Oct/30/2020 UNK: UNK	NO End Date Time:  Nov/7/2020 UNK:UNK	<a href="#">Repeating Pages</a>

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1095

**Subject No:** 10951101

**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

[Back to Form](#)  
[eCRF Audit Trail History](#)  
[Form Audit Trail](#)

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Pulmonary Embolism]
4.	Start Date Time:	Oct/30/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/7/2020 UNK:UNK
6.	Toxicity Grade:	3
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

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1095

**Subject No:** 10951101

**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

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: [HRT and prolonged immobilization]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020447041]

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (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:** 10951101

**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:** 10951101

**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

[Back to Form](#)

**Medication Error**

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

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**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:** 10951101

**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:** 10951101

**Subject Initials:** ---

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

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

[Back to Form](#)

**Concomitant Medications**

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

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (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:** 10951101

**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>

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1095

**Subject No:** 10951101

**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

[Back to Form](#)

**Concomitant Medications**

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

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (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:** 10951101

**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:** 10951101

**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

[Back to Form](#)

**Radiation Treatment**

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1095

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

**Subject No:** 10951101

**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>

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1095

**Subject No:** 10951101

**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

[Back to Form](#)

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1095

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

**Subject No:** 10951101

**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:** 10951101

**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:** LAB URINALYSIS - PREGNANCY TEST

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

**Form Status:** Not Started

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

**Lab Urinalysis**

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

**Lab Result**

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

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**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:** 10951101

**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?	

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (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:** 10951101

**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:** 10951101

**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:** V201\_SURVEIL\_CONSENT -  
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:** 10951101

**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:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

**Form Version:** 14-Jan-2021 02:29

**Form Status:** Not Started

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

**Informed Consent - Asymptomatic Surveillance**

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

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**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:** 10951101

**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:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**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:** 10951101

**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:** 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:** 10951101

**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/8/2021
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

**Site No:** 1095

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

**Subject No:** 10951101

**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 and NOT confirmed to have received only placebo at Vaccination 1/2
----	---	--



**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1095

**Subject No:** 10951101

**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/8/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** WITHDRAWAL OF CONSENT

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

**Form Status:** Not Started

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

**Withdrawal Of Consent**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1095

**Subject No:** 10951101

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

**Form:** DEATH DETAILS CODED

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Death Details**

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

**Cause of Death**

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

**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:** 10951101

**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	Sep/28/2020

**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:** 10951101

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Casebook Signature Form**

1.	Casebook Signature	<a href="#">Click Here to Enable</a>
----	--------------------	--------------------------------------

**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:** 10951101

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

**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951101

**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

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-13-2020 13:43:35 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001  
**Visit:** V1\_DAY1\_VAX1\_L  
**Form Version:** 30-Jul-2020 21:27  
**Site No:** 1095  
**Subject No:** 10951101  
**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments  
**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](#)

Item	Date	User	Comment
3	Aug-07-2020 19:02:05 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951101

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**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](#)

Item	Date	User	Comment
6.a	Aug-07-2020 19:02:45 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1095

**Subject No:** 10951101

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**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](#)

Item	Date	User	Comment
3	Aug-28-2020 10:16:10 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-10-2020 08:57:19 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** RESPIRATORY TREATMENT - Comments  
on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
1	Nov-10-2020 08:57:19 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
2	Nov-10-2020 08:57:19 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** RESPIRATORY TREATMENT - Comments  
on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
3	Nov-10-2020 08:57:19 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
4	Nov-10-2020 08:57:19 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** RESPIRATORY TREATMENT - Comments  
on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
5	Nov-10-2020 08:57:19 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
6	Nov-10-2020 08:57:19 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** ILLNESS DETAILS - SEVERE - Comments  
on Nov/05/2020

**Form Version:** 17-Jul-2020 21:55

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-10-2020 08:58:28 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** ILLNESS DETAILS - SEVERE - Comments  
on Nov/05/2020

**Form Version:** 17-Jul-2020 21:55

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
1	Nov-10-2020 08:58:28 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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

[Back to Form](#)

Item	Date	User	Comment
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**Generated Time (GMT):** 29-Mar-2021 10:39

[Back to Form](#)

Item	Date	User	Comment
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**Generated Time (GMT):** 29-Mar-2021 10:39

[Back to Form](#)

Item	Date	User	Comment
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**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/05/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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

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[Back to Form](#)

Item	Date	User	Comment
Form	Nov-10-2020 08:58:48 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Unknown

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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

[Back to Form](#)

Item	Date	User	Comment
5.b	Nov-10-2020 08:58:48 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Unknown



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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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

[Back to Form](#)

Item	Date	User	Comment
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**Header Text:** c4591001

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

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**Subject No:** 10951101

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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

[Back to Form](#)

Item	Date	User	Comment
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**Header Text:** c4591001

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

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

[Back to Form](#)

Item	Date	User	Comment
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**Form Version:** 30-Jul-2020 21:27

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

[Back to Form](#)

Item	Date	User	Comment
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**Generated Time (GMT):** 29-Mar-2021 10:39

[Back to Form](#)

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**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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

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**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
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**Header Text:** c4591001

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**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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

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**Subject No:** 10951101

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
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**Generated Time (GMT):** 29-Mar-2021 10:39

[Back to Form](#)

Item	Date	User	Comment
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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

Item	Date	User	Comment
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[Back to Form](#)

Item	Date	User	Comment
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[Back to Form](#)

Item	Date	User	Comment
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[Back to Form](#)

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

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

[Back to Form](#)

Item	Date	User	Comment
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**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

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

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

**Subject No:** 10951101

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-10-2020 08:59:03 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Unknown



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/05/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
1	Nov-10-2020 08:59:03 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Unknown

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

[Back to Form](#)

Item	Date	User	Comment
2	Nov-10-2020 08:59:03 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Unknown

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

[Back to Form](#)

Item	Date	User	Comment
3	Nov-10-2020 08:59:03 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Unknown

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

[Back to Form](#)

Item	Date	User	Comment
4	Nov-10-2020 08:59:03 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Unknown

**Header Text:** c4591001

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**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
5.a	Nov-10-2020 08:59:03 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Unknown

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/05/2020

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

Item	Date	User	Comment
5.b	Nov-10-2020 08:59:03 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Unknown

**Header Text:** c4591001

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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

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

[Back to Form](#)

Item	Date	User	Comment
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**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

Item	Date	User	Comment
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**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
5.d	Nov-10-2020 08:59:03 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Unknown

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/05/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

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

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**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
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**Generated Time (GMT):** 29-Mar-2021 10:39

[Back to Form](#)

Item	Date	User	Comment
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**Generated Time (GMT):** 29-Mar-2021 10:39

[Back to Form](#)

Item	Date	User	Comment
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**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
5.e	Nov-10-2020 08:59:03 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Unknown

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/05/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

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

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**Subject No:** 10951101

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
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**Generated Time (GMT):** 29-Mar-2021 10:39

[Back to Form](#)

Item	Date	User	Comment
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[Back to Form](#)

Item	Date	User	Comment
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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/05/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
5.i	Nov-10-2020 08:59:03 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Unknown

**Header Text:** c4591001

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[Back to Form](#)

Item	Date	User	Comment
5.i	Nov-10-2020 08:59:03 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Unknown



**Header Text:** c4591001

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**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

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

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

[Back to Form](#)

Item	Date	User	Comment
5.j	Nov-10-2020 08:59:03 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Unknown

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/05/2020

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

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

[Back to Form](#)

Item	Date	User	Comment
5.j	Nov-10-2020 08:59:03 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Unknown

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/05/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

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

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

**Site No:** 1095

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

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

[Back to Form](#)

Item	Date	User	Comment
5.j	Nov-10-2020 08:59:03 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Unknown

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/05/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
5.j	Nov-10-2020 08:59:03 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Unknown

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Comments  
on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-10-2020 09:04:00 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Unknown
Form	Nov-10-2020 09:02:21 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Comments  
on Nov/05/2020

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

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

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
1	Nov-10-2020 09:04:00 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Unknown
1	Nov-10-2020 09:02:21 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** VITAL SIGNS - COVID - Comments  
on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
2.a	Nov-10-2020 09:04:00 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Unknown
2.a	Nov-10-2020 09:02:21 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** VITAL SIGNS - COVID - Comments  
on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
2.a	Nov-10-2020 09:04:00 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Unknown
2.a	Nov-10-2020 09:02:21 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** VITAL SIGNS - COVID - Comments  
on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
2.a	Nov-10-2020 09:04:00 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Unknown
2.a	Nov-10-2020 09:02:21 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** VITAL SIGNS - COVID - Comments  
on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
2.a	Nov-10-2020 09:04:00 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Unknown
2.a	Nov-10-2020 09:02:21 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments  
on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-10-2020 09:03:39 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Unknown

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments  
on Nov/05/2020

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

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

**Site No:** 1095

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**Subject No:** 10951101

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

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

[Back to Form](#)

Item	Date	User	Comment
1	Nov-10-2020 09:03:39 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Unknown

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments  
on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
2.a	Nov-10-2020 09:03:39 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Unknown

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments  
on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-10-2020 09:04:15 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Unknown

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments  
on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
1	Nov-10-2020 09:04:15 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Unknown

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments  
on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
2	Nov-10-2020 09:04:15 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Unknown



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments  
on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
3	Nov-10-2020 09:04:15 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Unknown

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/05/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-10-2020 09:04:28 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Unknown

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/05/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
1	Nov-10-2020 09:04:28 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Unknown

**Header Text:** c4591001

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**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

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[Back to Form](#)

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[Back to Form](#)

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**Header Text:** c4591001

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**Site No:** 1095

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

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

[Back to Form](#)

Item	Date	User	Comment
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/05/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
5	Nov-10-2020 09:04:28 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Unknown

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/05/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[Back to Form](#)

Item	Date	User	Comment
6	Nov-10-2020 09:04:28 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Unknown



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: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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
(b) (6)	N/A	Feb-17-2021 09:55:51 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

**Affidavit:**

N/A

Paul Pickrell	Approved	Jan-25-2021 21:14:13 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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**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.

(b) (6)	N/A	Nov-20-2020 16:06:09 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Paul Pickrell	Approved	Nov-14-2020 07:21:09 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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**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.

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

(b) (6)	N/A	Nov-11-2020 08:07:27 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Paul Pickrell	Approved	Nov-10-2020 21:14:47 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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**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.

(b) (6)	N/A	Nov-10-2020 08:40:28 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Paul Pickrell	Approved	Oct-14-2020 07:40:59 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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**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.

(b) (6)	N/A	Sep-28-2020 10:36:02 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

Paul Pickrell	Approved	Sep-22-2020 17:09:13 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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**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.

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1095

**Subject No:** 10951101

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

**Form:** COHORT\_SELECTION - 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. Select appropriate response - Protocol version**

Date	Location	User	Value	Reason
Aug-07-2020 18:36:32 (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
Aug-07-2020 18:36:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1095

**Subject No:** 10951101

**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

[Back to Form](#)

**I. Consent Was:**

Date	Location	User	Value	Reason
Aug-07-2020 18:36:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Aug/7/2020	Initial Entry

Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1095

Subject No: 10951101

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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Aug-07-2020 18:36:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10951101	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-07-2020 18:36:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6) 1954	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-21-2020 05:39:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Cl osed	Per site confirmation
Aug-20-2020 07:48:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: A nswered	This has been completed.
Aug-17-2020 06:57:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: R eissued:Op ened	DM query: Kindly confirm once the data in IMPALA has been updated. Thank you.
Aug-10-2020 18:58:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: A nswered	Data correction form sent to Impala for information change.

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: COHORT\_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

Aug-10-2020 09:47:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: O pened	As per Impala, Sex is recorded as Male. Please review and update as appropriate. (b) (4)
Aug-07-2020 18:37:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Aug-07-2020 18:37:08 (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
Aug-07-2020 18:37:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:02

Site No: 1095

Subject No: 10951101

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

[Back to Form](#)

*I. Date of Visit*

Date	Location	User	Value	Reason
Aug-14-2020 01:27:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed by DM: (b) (6)
Aug-13-2020 13:44:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	This has been updated
Aug-13-2020 01:05:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Inclusion/Exclusion criteria have been added, vaccination details present. Inclusion/Exclusion is expected only for Screen Failure and subjects randomized in error. Please add Form level comment "Not Applicable" if Incl/Excl was added in error or confirm.
Aug-07-2020 18:37:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/7/2020	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951101

**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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Aug-07-2020 18:37:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/7/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Aug-07-2020 18:37:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Aug-07-2020 18:37:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1095**Subject No:** 10951101**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[Back to Form](#)**I.a**

Date	Location	User	Value	Reason
Aug-07-2020 18:39:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 1 <b>Medical History</b> torn right ankle tendon <b>Term:</b> <b>Start Date:</b> UNK/UNK/2017 <b>Ongoing:</b> NO End Date:  UNK/UNK/2017	Initial Entry

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

Date	Location	User	Value	Reason
Aug-07-2020 18:39:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-07-2020 18:39:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> torn right ankle tendon	Initial Entry

**I.a Start Date:**

Date	Location	User	Value	Reason
Aug-07-2020 18:39:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2017	Initial Entry

**I.a Ongoing:**

Date	Location	User	Value	Reason
Aug-07-2020 18:39:11	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951101

**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

(UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	NO End Date:  UNK/UNK/2017
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*I.b*

Date	Location	User	Value	Reason
Aug-07-2020 18:39:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 2 <b>Medical History Term:</b> ankle surgery (right ankle) <b>Start Date:</b> UNK/UNK/2017 <b>Ongoing:</b> NO End Date: UNK/UNK/2017	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951101

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.b Line/MH Number:**

Date	Location	User	Value	Reason
Aug-07-2020 18:39:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-07-2020 18:39:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ankel surgery (right ankle)	Initial Entry

**1.b Start Date:**

Date	Location	User	Value	Reason
Aug-07-2020 18:39:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2017	Initial Entry

**1.b Ongoing:**

Date	Location	User	Value	Reason
Aug-07-2020 18:39:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2017	Initial Entry

**1.c**

Date	Location	User	Value	Reason
Aug-07-2020 18:39:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number</b> 3 : <b>Medical History Term:</b> cataracts (bilat eral) <b>Start Date:</b> UNK/UNK/20 19 <b>Ongoing:</b> YES	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951101

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.c Line/MH Number:**

Date	Location	User	Value	Reason
Aug-07-2020 18:39:59 (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
Aug-07-2020 18:39:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> cataracts (bilateral)	Initial Entry

**I.c Start Date:**

Date	Location	User	Value	Reason
Aug-07-2020 18:39:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2019	Initial Entry

**I.c Ongoing:**

Date	Location	User	Value	Reason
Aug-07-2020 18:39:59 (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
Aug-07-2020 18:45:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 4 <b>Medical History Term:</b> jaw surgery- fix misalignment <b>Start Date:</b> UNK/UNK/2000 <b>Ongoing:</b> NO End Date: UNK/UNK/2000	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951101

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.d Line/MH Number:**

Date	Location	User	Value	Reason
Aug-07-2020 18:45:13 (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
Aug-07-2020 18:45:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> jaw surgery- fix misalignment	Initial Entry

**1.d Start Date:**

Date	Location	User	Value	Reason
Aug-07-2020 18:45:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2000	Initial Entry

**1.d Ongoing:**

Date	Location	User	Value	Reason
Aug-07-2020 18:45:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2000	Initial Entry

**1.e**

Date	Location	User	Value	Reason
Aug-07-2020 18:46:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 5 <b>Medical History Term:</b> congenital jaw misalignment <b>Start Date:</b> (b) (6) 1954	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951101

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

			Ongoing: NO End Date:  UNK/UNK/2000	
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*I.e Line/MH Number:*

Date	Location	User	Value	Reason
Aug-07-2020 18:46:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 5	Initial Entry

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

Date	Location	User	Value	Reason
Aug-07-2020 18:46:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> congenital jaw misalignment	Initial Entry

*I.e Start Date:*

Date	Location	User	Value	Reason
Aug-07-2020 18:46:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> (b) (6) 1954	Initial Entry

*I.e Ongoing:*

Date	Location	User	Value	Reason
Aug-07-2020 18:46:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO End Date:  UNK/UNK/2000	Initial Entry

*I.f*

Date	Location	User	Value	Reason
Aug-07-2020 18:49:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Number: 6	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951101

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> partial knee replacement (left) <b>Start Date:</b> UNK/UNK/2011 <b>Ongoing:</b> NO End Date: UNK/UNK/2011	
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*1.f Line/MH Number:*

Date	Location	User	Value	Reason
Aug-07-2020 18:49:24 (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
Aug-07-2020 18:49:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> partial knee replacement (left)	Initial Entry

*1.f Start Date:*

Date	Location	User	Value	Reason
Aug-07-2020 18:49:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2011	Initial Entry

*1.f Ongoing:*

Date	Location	User	Value	Reason
Aug-07-2020 18:49:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: UNK/UNK/2011	Initial Entry

*1.g*

Date	Location	User	Value	Reason
Aug-07-2020 18:49:46	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951101

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

(UTC-06:00) Central Time (US & Canada)		(autocalc)	Line/MH Number: 7 Medical History Term: partial knee replacement (right) Start Date: UNK/UNK/2013 Ongoing: NO End Date: UNK/UNK/2013
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**I.g Line/MH Number:**

Date	Location	User	Value	Reason
Aug-07-2020 18:49:46 (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
Aug-07-2020 18:49:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> partial knee replacement (right)	Initial Entry

**I.g Start Date:**

Date	Location	User	Value	Reason
Aug-07-2020 18:49:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2013	Initial Entry

**I.g Ongoing:**

Date	Location	User	Value	Reason
Aug-07-2020 18:49:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: UNK/UNK/2013	Initial Entry

**I.h**

Date	Location	User	Value	Reason
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090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951101

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

Aug-07-2020 18:50:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Nu</b> 8 <b>mber:</b> <b>Medical Hist</b> cartilage deterioratio <b>ory Term:</b> n (both knees) <b>Start Date:</b> UNK/UNK/2011 <b>Ongoing:</b> NO End Date:  UNK/UNK/2013	Initial Entry
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**1.h Line/MH Number:**

Date	Location	User	Value	Reason
Aug-07-2020 18:50:47 (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
Aug-07-2020 18:50:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> cartilage deterioration (both knees )	Initial Entry

**1.h Start Date:**

Date	Location	User	Value	Reason
Aug-07-2020 18:50:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2011	Initial Entry

**1.h Ongoing:**

Date	Location	User	Value	Reason
Aug-07-2020 18:50:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2013	Initial Entry

**1.i**

Date	Location	User	Value	Reason
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090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951101

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

Aug-07-2020 18:51:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 9 <b>Medical History T</b> migraines <b>erm:</b> <b>Start Date:</b> UNK/UNK/1 985 <b>Ongoing:</b> YES	Initial Entry
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**1.i Line/MH Number:**

Date	Location	User	Value	Reason
Aug-07-2020 18:51:23 (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
Aug-07-2020 18:51:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> migraines	Initial Entry

**1.i Start Date:**

Date	Location	User	Value	Reason
Aug-07-2020 18:51:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1985	Initial Entry

**1.i Ongoing:**

Date	Location	User	Value	Reason
Aug-07-2020 18:51:23 (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
Aug-11-2020 14:18:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Line/MH Num</b> 10 <b>ber:</b>	Transcription Error

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951101

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> mitral valve prolapse <b>Start Date:</b> UNK/UNK/2005 <b>Ongoing:</b> YES	
Aug-10-2020 18:58:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Line/MH Number:</b> 10 <b>Medical History Term:</b> mitral valve prolapse <b>Start Date:</b> UNK/UNK/2005 <b>Ongoing:</b> NO <b>End Date:</b> UNK/UNK/2005	Transcription Error
Aug-07-2020 18:52:52 (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> mitral valve prolapse <b>Start Date:</b> UNK/UNK/2005 <b>Ongoing:</b> NO <b>End Date:</b> UNK/UNK/2005	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951101

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

Date	Location	User	Value	Reason
Aug-07-2020 18:52:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10	Initial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 12:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951101

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Aug-11-2020 14:19:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	updated
Aug-11-2020 08:30:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 2: Closed	Response satisfies query
Aug-11-2020 08:30:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Reissued: Opened	Please confirm if the mitral valve prolapse is still present as it is not typically self-curable. If it is not present, please add the procedure performed to treat this condition as a separate medical history.
Aug-10-2020 18:58:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Aug-10-2020 18:58:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Aug-10-2020 18:58:52 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> mitral valve prolapse	Transcription Error

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951101

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

(US & Canada)				
Aug-10-2020 16:50:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 2: Opened	In addition to the misspell of "valve", please confirm if the condition is still present as it is not typically self-curable. If it is not present, please add the procedure curing this condition as a separate medical history.
Aug-07-2020 19:45:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify MITRAL VALUE PROLAPSE as follows...Should spelling be MITRAL VALVE PROLAPSE? If so, edit. Otherwise clarify. Thank you.
Aug-07-2020 18:52:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> mitral value prolapse	Initial Entry

***1.j Start Date:***

Date	Location	User	Value	Reason
Aug-07-2020 18:52:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2005	Initial Entry

***1.j Ongoing:***

Date	Location	User	Value	Reason
Aug-11-2020 14:18:49	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951101

**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

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	YES	
Aug-07-2020 18:52:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2005	Initial Entry

*I.k*

Date	Location	User	Value	Reason
Aug-07-2020 18:53:08 (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> seasonal allergies <b>Start Date:</b> UNK/UNK/2010 <b>Ongoing:</b> YES	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951101

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.k Line/MH Number:**

Date	Location	User	Value	Reason
Aug-07-2020 18:53:08 (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
Aug-07-2020 18:53:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> seasonal allergies	Initial Entry

**1.k Start Date:**

Date	Location	User	Value	Reason
Aug-07-2020 18:53:08 (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
Aug-07-2020 18:53:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.l**

Date	Location	User	Value	Reason
Aug-07-2020 18:53:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 12 <b>Medical History:</b> tonsillitis <b>Term:</b> <b>Start Date:</b> UNK/UNK/1965 <b>Ongoing:</b> NO End Date: UNK/UNK/ 1965	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951101

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

1.1 Line/MH Number:

Date	Location	User	Value	Reason
Aug-07-2020 18:53:38 (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
Aug-07-2020 18:53:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> tonsillitis	Initial Entry

1.1 Start Date:

Date	Location	User	Value	Reason
Aug-07-2020 18:53:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1965	Initial Entry

1.1 Ongoing:

Date	Location	User	Value	Reason
Aug-07-2020 18:53:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/1965	Initial Entry

1.m

Date	Location	User	Value	Reason
Aug-07-2020 18:54:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 13 <b>r:</b> <b>Medical History Term:</b> tonsillectomy <b>Start Date:</b> UNK/UNK/1965	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951101

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/ 1965	

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

Date	Location	User	Value	Reason
Aug-07-2020 18:54:41 (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
Aug-07-2020 18:54:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> tonsillectomy	Initial Entry

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

Date	Location	User	Value	Reason
Aug-07-2020 18:54:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1965	Initial Entry

***1.m Ongoing:***

Date	Location	User	Value	Reason
Aug-07-2020 18:54:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/1965	Initial Entry

***1.n***

Date	Location	User	Value	Reason
Aug-07-2020 18:55:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Num 14 ber:</b>	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951101

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> postmenopausal symptoms <b>Start Date:</b> UNK/UNK/2009 <b>Ongoing:</b> YES	
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**I.n Line/MH Number:**

Date	Location	User	Value	Reason
Aug-07-2020 18:55:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 14	Initial Entry

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

Date	Location	User	Value	Reason
Aug-07-2020 18:55:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> postmenopausal symptoms	Initial Entry

**I.n Start Date:**

Date	Location	User	Value	Reason
Aug-07-2020 18:55:57 (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
Aug-07-2020 18:55:57 (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
Aug-28-2020 17:22:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 15 <b>Medical History Term:</b> hepatitis B	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951101

**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>Start Date:</b>	UNK/UNK/198 1	
			<b>Ongoing:</b>	NO	
				End Date:	
				UNK/UNK/ 1981	

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951101

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.o Line/MH Number:**

Date	Location	User	Value	Reason
Aug-28-2020 17:22:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 15	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 11:21:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-01-2020 09:36:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	This has been updated
Aug-31-2020 19:39:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Please provide the source in Complion under Medical History, thanks
Aug-28-2020 17:22:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> hepatitis B	Initial Entry

**I.o Start Date:**

Date	Location	User	Value	Reason
Aug-28-2020 17:22:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1981	Initial Entry

**I.o Ongoing:**

Date	Location	User	Value	Reason
Aug-28-2020 17:22:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: UNK/UNK/1981	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:28

Site No: 1095

Subject No: 10951101

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

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Aug-07-2020 19:01:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/7/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Aug-07-2020 19:01:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 99.3	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Aug-07-2020 19:01:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Aug-07-2020 19:01:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 173.5	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Aug-07-2020 19:01:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> cm	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Aug-07-2020 19:01:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 33.0	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:28

Site No: 1095

Subject No: 10951101

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

7.a

Date	Location	User	Value	Reason
Aug-07-2020 19:01:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> 1 : <b>Temperature:</b> 98.6 <b>Temperature Unit</b> F : <b>Temperature Loca</b> ORAL CAV <b>tion::</b> ITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-07-2020 19:01:48 (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
Aug-07-2020 19:01:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 98.6	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-07-2020 19:01:48 (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
Aug-07-2020 19:01:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

3. Collection Date:

Date	Location	User	Value	Reason
Aug-07-2020 19:02:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-07-2020 19:02:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> Not Applicable <b>Not Done::</b> NOT DONE	Initial Entry
Aug-07-2020 19:02:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> Not Applicable <b>Not Done::</b>	Initial Entry
Aug-07-2020 19:02:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> <b>Not Done::</b>	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-07-2020 19:02:57 (UTC-06:00) Central Time	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

(US & Canada)				
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6.a Test:

Date	Location	User	Value	Reason
Aug-07-2020 19:02:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-07-2020 19:02:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Aug-07-2020 19:02:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951101

**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

[Back to Form](#)

**1. Randomization Date :**

Date	Location	User	Value	Reason
Aug-07-2020 19:03:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/7/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Aug-07-2020 19:03:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 224159	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (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: 10951101

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
Aug-07-2020 19:06:26 (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
Aug-07-2020 19:06:26 (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
Aug-07-2020 19:06:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-07-2020 19:06:26 (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.
Aug-07-2020 19:06:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/7/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-07-2020 19:06:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP3BXX	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (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: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Aug-07-2020 19:06:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP3BXX	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-07-2020 19:06:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP3BXL	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-07-2020 19:06:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP3BXL	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-07-2020 19:06:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP3BXM	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-07-2020 19:06:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP3BXM	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-07-2020 19:07:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPLJJD	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (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:** 10951101

**Subject Initials:** ---

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

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

**5.d Sample ID**

Date	Location	User	Value	Reason
Aug-07-2020 19:07:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPLJJD	Initial Entry

**5.e**

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

**5.e Sample ID**

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

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (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: 10951101

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
Aug-07-2020 19:07:25 (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
Aug-07-2020 19:07:25 (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
Aug-07-2020 19:07:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-07-2020 19:07:25 (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.
Aug-07-2020 19:07:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/7/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-07-2020 19:07:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP3BB3	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (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:** 10951101

**Subject Initials:** ---

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

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

**5.a Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Aug-07-2020 19:07:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u><b>Data Entry:</b></u> BP3BB3	Initial Entry



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1095

Subject No: 10951101

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Aug-07-2020 19:04:00 (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
Aug-07-2020 19:04:00 (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
Aug-07-2020 19:04:00 (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
Aug-07-2020 19:04:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/7/2020 15:10	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-07-2020 19:04:00 (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
Aug-07-2020 19:04:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1095

Subject No: 10951101

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

7. Route:

Date	Location	User	Value	Reason
Aug-07-2020 19:04:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-07-2020 19:04:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-07-2020 19:04:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951101

**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

[Back to Form](#)

*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Aug-07-2020 19:04:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES - REACTOGENICITY E-DI ARY COLLECTED FOR THIS S UBJECT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1095

**Subject No:** 10951101

**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

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Aug-28-2020 10:12:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/28/2020	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Aug-28-2020 10:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-28-2020 10:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FE VE R <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> N O	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Aug-28-2020 10:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 10:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Aug-28-2020 10:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FA TIG UE	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Aug-28-2020 10:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 10:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Aug-28-2020 10:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Symptom::</u> HE AD AC HE  Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

2.c Symptom:

Date	Location	User	Value	Reason
Aug-28-2020 10:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 10:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Aug-28-2020 10:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> CH IL LS  <b>Were fever or systemic sym</b> NO <b>ptoms present on the last d</b> <b>ay the Subject Diary was co</b> <b>mpleted?:</b>	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Aug-28-2020 10:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 10:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
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090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

Aug-28-2020 10:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b>  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	Initial Entry
			VO MIT ING NO	

2.e Symptom:

Date	Location	User	Value	Reason
Aug-28-2020 10:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 10:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Aug-28-2020 10:16:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b>  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	Transcription Error
			DIARRH EA YES Ongoing ? NO  Stop Date:  Au g/1 3/2 020	

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

<p>Aug-28-2020 10:15:48 (UTC-06:00) Central Time (US &amp; Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p><b>Data Entry:</b> <b>Symptom::</b> DIARRH EA <b>Were fever or system ic symptoms present on the last day the Su bject Diary was com pleted?:</b> YES Ongoing ? NO  Stop Date:  Au g/1 3/2 021</p>	<p>Initial Entry</p>
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090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

2.f Symptom:

Date	Location	User	Value	Reason
Aug-28-2020 10:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 10:16:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-28-2020 10:16:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Ongoing?  NO  Stop Date:  Aug/13/2020	Transcription Error
Aug-28-2020 10:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Symptom Stop Date is a future date relative to when it was entered. Please correct.
Aug-28-2020 10:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Ongoing?  NO  Stop Date:  Aug/13/2021	Initial Entry

2.g

Date	Location	User	Value	Reason
Aug-28-2020 10:15:48 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)	(b) (4), (b) (6)	WORSE ED MUS CLE PAI N	Were fever or system ic symptoms present on the last day the Su bject Diary was com pleted?:	NO
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2.g Symptom:

Date	Location	User	Value	Reason
Aug-28-2020 10:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR WORSE NED MUSCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 10:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Aug-28-2020 10:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Symptom::</u> NEW OR WORSE NED JOI NT PAIN	Initial Entry
			Were fever or systemi c symptoms present o n the last day the Sub ject Diary was compl eted?:	NO

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

2.h Symptom:

Date	Location	User	Value	Reason
Aug-28-2020 10:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENERD JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 10:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Aug-28-2020 10:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Aug-28-2020 10:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-28-2020 10:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> RE DN ESS <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
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090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

Aug-28-2020 10:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> REDNESS	Initial Entry
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5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-28-2020 10:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-28-2020 10:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Injection Site Reaction:: SWE LLI NG  Were injection site reactio ns present on the last day the Subject Diary was co mpleted?: NO	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-28-2020 10:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 10:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-28-2020 10:15:48 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Injection Site Reaction PAIN A	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)		(b) (4), (b) (6)	::	T INJECTION SITE	
Were injection site reactions present on the last day the Subject Diary was completed?: NO					

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-28-2020 10:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 10:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 21-Aug-2020 02:51

Site No: 1095

Subject No: 10951101

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

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Aug-28-2020 10:17:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/28/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Aug-28-2020 10:17:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 98.1 <b>Temperature Unit:</b> F <b>Temperature Location::</b> ORAL CAVITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Aug-28-2020 10:17:35 (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
Aug-28-2020 10:17:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 98.1	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Aug-28-2020 10:17:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

**2.a Temperature Location:**

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1095

**Subject No:** 10951101

**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

Date	Location	User	Value	Reason
Aug-28-2020 10:17:35 (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: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

3. Collection Date:

Date	Location	User	Value	Reason
Aug-28-2020 10:16:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-28-2020 10:16:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> <b>Not Done::</b> NOT DONE	Initial Entry
Aug-28-2020 10:16:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> <b>Not Done::</b>	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-28-2020 10:16:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-28-2020 10:16:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

**6.a Not Done:**

Date	Location	User	Value	Reason
Aug-28-2020 10:16:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	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: 10951101

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
Aug-28-2020 10:14:48 (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
Aug-28-2020 10:14:48 (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
Aug-28-2020 12:05:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-28-2020 10:14:48 (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.
Aug-28-2020 10:14:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/28/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-28-2020 12:05:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BP3BGL</b>	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

**5.a Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Aug-28-2020 12:05:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP3BGL	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1095

Subject No: 10951101

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Aug-28-2020 10:13:05 (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
Aug-28-2020 10:13:05 (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
Aug-28-2020 10:13:05 (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
Aug-28-2020 10:13:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/28/2020 09:53	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-28-2020 10:13:05 (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
Aug-28-2020 10:13:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1095

Subject No: 10951101

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

7. Route:

Date	Location	User	Value	Reason
Aug-28-2020 10:13:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-28-2020 10:13:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-28-2020 10:13:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951101

**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

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Sep-28-2020 10:36:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/28/2020	Initial Entry

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1095**Site Name:** (1095) Tekton Research**Subject No:** 10951101**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Sep-28-2020 10:46:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-28-2020 10:46:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FE VE R <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> N O	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Sep-28-2020 10:46:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Sep-28-2020 10:46:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Sep-28-2020 10:46:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FA TIG UE	Initial Entry



**Header Text:** c4591001  
**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History  
**Form Version:** 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1095 **Site Name:** (1095) Tekton Research  
**Subject No:** 10951101 **Subject Initials:** ---  
**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:39

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

Date	Location	User	Value	Reason
Sep-28-2020 10:46:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-28-2020 10:46:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.c**

Date	Location	User	Value	Reason
Sep-28-2020 10:46:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> HE AD AC HE <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

2.c Symptom:

Date	Location	User	Value	Reason
Sep-28-2020 10:46:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-28-2020 10:46:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-28-2020 10:46:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> CH IL LS  <b>Were fever or systemic sym</b> NO <b>ptoms present on the last da</b> <b>y the Subject Diary was co</b> <b>mpleted?:</b>	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Sep-28-2020 10:46:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-28-2020 10:46:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
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090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

Sep-28-2020 10:46:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b>  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	Initial Entry
			VO MIT ING NO	

2.e Symptom:

Date	Location	User	Value	Reason
Sep-28-2020 10:46:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-28-2020 10:46:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-28-2020 10:46:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b>  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	Initial Entry
			DIA RR HE A NO	

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

2.f Symptom:

Date	Location	User	Value	Reason
Sep-28-2020 10:46:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Sep-28-2020 10:46:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-28-2020 10:46:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE NED MUS CLE PAI N  <b>Were fever or system NO ic symptoms present on the last day the Su bject Diary was com pleted?:</b>	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Sep-28-2020 10:46:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSE NED MUSCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-28-2020 10:46:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

2.h

Date	Location	User	Value	Reason
Sep-28-2020 10:46:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE NED JOINT PAIN  Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Sep-28-2020 10:46:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSE JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-28-2020 10:46:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-28-2020 10:46:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-28-2020 10:46:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

5.a

Date	Location	User	Value	Reason
Sep-28-2020 10:46:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> RE DN ESS  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-28-2020 10:46:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-28-2020 10:46:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-28-2020 10:46:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> SWE LLI NG  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-28-2020 10:46:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-28-2020 10:46:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-28-2020 10:46:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Injection Site Reaction PAIN AT INJECTION SITE  Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-28-2020 10:46:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-28-2020 10:46:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (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: 10951101

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
Sep-28-2020 10:47:05 (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
Sep-28-2020 10:47:05 (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
Sep-28-2020 18:14:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-28-2020 10:47:05 (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.
Sep-28-2020 10:47:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/28/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-28-2020 18:14:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPY2LW	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (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: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Sep-28-2020 18:14:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPY2LW	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-28-2020 18:14:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPY2LX	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-28-2020 18:14:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPY2LX	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-28-2020 18:14:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPY2LY	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-28-2020 18:14:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPY2LY	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-28-2020 18:14:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPCTC0	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (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: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sample ID

Date	Location	User	Value	Reason
Sep-28-2020 18:14:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPCTC0	Initial Entry

5.e

Date	Location	User	Value	Reason
Sep-28-2020 18:14:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPCTC1	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Sep-28-2020 18:14:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPCTC1	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: V4\_MONTH6\_L

Form Version: 22-Apr-2020 21:02

Site No: 1095

Subject No: 10951101

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

[Back to Form](#)

*I. Date of Visit*

Date	Location	User	Value	Reason
Mar-11-2021 00:14:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed per SITE response, added to PD tracker for Clinical Review.
Mar-10-2021 09:06:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Correct, visit is out of window, pd to be recorded on site pd log.
Mar-10-2021 04:41:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	PDQ: Date of visit at V4_MONTH6_L is out of window for 3 days from V2_VAX2_L DOV or V2 Vaccination date. Please verify and update. Else, confirm in query response appropriately. (b) (4)
Mar-08-2021 14:34:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/8/2021	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: V4\_MONTH6\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

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
Mar-08-2021 14:34:20 (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
Mar-08-2021 14:34:20 (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
Mar-10-2021 08:47:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-09-2021 04:51:57 (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.
Mar-08-2021 14:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-08-2021 14:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Mar/8/2021	Initial Entry

5.a

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: V4\_MONTH6\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Mar-10-2021 08:47:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRBTNN	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-10-2021 08:47:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRBTNN	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-10-2021 08:47:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRBTNP	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-10-2021 08:47:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRBTNP	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-10-2021 08:48:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRBTNR	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-10-2021 08:48:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRBTNR	Initial Entry

5.d

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Mar-11-2021 13:18:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPCTMY	Initial Entry

**5.d Sample ID**

Date	Location	User	Value	Reason
Mar-11-2021 13:18:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPCTMY	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/05/2020

Form: DATE OF VISIT - ILLNESS ONSET - 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: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

*I. Date of Visit*

Date	Location	User	Value	Reason
Mar-09-2021 03:55:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Mar-03-2021 14:35:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Visit was not conducted, participant not willing to return for visit since illness was related to pulmonary embolism not COVID.
Mar-01-2021 09:44:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	Convalescent visit is expected 28-35 days after illness visit, but no convalescent visit is entered. Please conduct a convalescent visit and complete data entry or respond with reason visit is not expected. If scheduled, please provide date expected
Nov-13-2020 00:42:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	As per site confirmation - updated PD tracker
Nov-12-2020 10:06:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Illness visit took place, however participant was diagnosed with pulmonary embolism, not COVID-19. She did have testing in the

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

				hospital that was negative.
Nov-11-2020 02:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	PDQ : Details of Sample ID and collection date for either Nasal Swab Self or Nasal Swab expected to be completed. Please check and update else clarify.
Nov-11-2020 00:53:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	As per the response in #4 in Swab form
Nov-10-2020 08:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Nov-10-2020 08:48:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Nov-10-2020 08:48:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Nov-10-2020 08:48:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/5/2020	Initial Entry

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

Date	Location	User	Value	Reason
Nov-10-2020 08:48:16	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Initial Entry



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

(UTC-06:00) Central Time (US & Canada)		(autocalc)	COVID_A	
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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/05/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

**1. Date of Assessment:**

Date	Location	User	Value	Reason
Nov-10-2020 08:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/5/2020	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Nov-10-2020 08:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/30/2020	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Feb-17-2021 12:32:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-17-2021 09:55:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	updated
Feb-17-2021 09:55:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Date of Last Symptom Resolved:  Nov/7/2020	updated
Feb-14-2021 23:02:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Please confirm the symptoms are still ongoing for this COVID illness. If all symptoms for this illness are resolved; please update the Last Symptoms

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/05/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

				Resolved Date else clarify. Thanks
Nov-10-2020 08:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Nov-10-2020 08:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> FEVER <b>Symptom Present:</b> NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 08:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 08:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Nov-10-2020 08:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED COUGH <b>Symptom P present:</b> YES	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Nov/05/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF  
Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1095**Site Name:** (1095) Tekton Research**Subject No:** 10951101**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39**4.b Symptoms:**

Date	Location	User	Value	Reason
Nov-10-2020 08:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED COUGH	Initial Entry

**4.b Was symptom present?**

Date	Location	User	Value	Reason
Nov-10-2020 08:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.c**

Date	Location	User	Value	Reason
Nov-10-2020 08:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom:</b> NEW OR INCREASED SHORTNESS OF BREATH <b>Symptom Present:</b> YES	Initial Entry

**4.c Symptoms:**

Date	Location	User	Value	Reason
Nov-10-2020 08:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

**4.c Was symptom present?**

Date	Location	User	Value	Reason
Nov-10-2020 08:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.d**

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/05/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

Nov-10-2020 08:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> CHILLS <b>Symptom Present:</b> NO	Initial Entry
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4.d Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 08:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 08:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Nov-10-2020 08:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom</b> NEW OR INCREASED MUSCLE PAIN <b>Symptom Present:</b> NO	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 08:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 08:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.f

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/05/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Nov-10-2020 08:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms NEW LOSS OF TASTE OR SMELL Symptom NO Present:	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 08:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 08:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Nov-10-2020 08:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptom NEW OR INCREASED SORE THROAT Symptom NO Present:	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/05/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

4.g Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 08:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SORE T HROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 08:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Nov-10-2020 08:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> DIARRHEA <b>Symptom Present:</b> NO	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 08:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 08:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Nov-10-2020 08:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> VOMITING <b>Symptom Present:</b> NO	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Nov/05/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF  
Audit Trail History

**Form Version:** 10-Oct-2020 16:02

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

**4.i Symptoms:**

Date	Location	User	Value	Reason
Nov-10-2020 08:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

**4.i Was symptom present?**

Date	Location	User	Value	Reason
Nov-10-2020 08:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Audit Trail  
on Nov/05/2020

**Form Version:** 06-Jul-2020 21:54

**Form Status:**

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-10-2020 08:50:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Nov/05/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Nov-10-2020 08:50:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/3/2020	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Nov-10-2020 08:50:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWABBED MATERIAL	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Nov-10-2020 08:50:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NASOPHARYNX	Initial Entry

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
Nov-10-2020 08:50:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE ACUTE RESP SYNDRO ME CORONAVIRUS 2	Initial Entry

**5. Device Type:**

Date	Location	User	Value	Reason
Nov-10-2020 08:50:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SARS-COV-2 DIAGNOSTIC TES T	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
Nov-10-2020 08:50:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Nov/05/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

7. Test Result:

Date	Location	User	Value	Reason
Nov-10-2020 08:50:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Nov-11-2020 12:48:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-11-2020 08:07:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Nov-11-2020 08:07:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NALT unknown	Transcription Error
Nov-11-2020 05:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 2: Opened	As per CRF CR, If trade name is not known. Please update "NALT Unknown" in the specified field, Thank you. (b) (4)
Nov-10-2020 13:18:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Paper source update

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History  
on Nov/05/2020

**Form Version:** 06-Jul-2020 21:54

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

Nov-10-2020 11:04:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: O pened	Please provide the source, thanks
Nov-10-2020 08:50:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entr</b> <b>y:</b> NAAT Un known	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/05/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - 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: 10951101

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
Nov-10-2020 08:52:19 (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
Nov-10-2020 08:52:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-04-2021 02:48:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-03-2021 12:21:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Data is correct, that is when participant was agreeable to swab
Feb-17-2021 09:55:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Date of Collection is more than 4 days after Date of Last Symptom Resolved on the Signs and Symptoms form in the same visit. Please review and update as appropriate.
Nov-20-2020 16:06:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-20-2020 16:06:46 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	New Information

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/05/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - 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: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)		(b) (4), (b) (6)	Date of Collection: Nov/16/2020	
Nov-20-2020 16:06:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Sample Collected?" is No, but Barcodes are present on the page.
Nov-10-2020 08:52:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Nov-20-2020 16:07:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	New Information
Nov-10-2020 09:23:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Subject instructed to collect hom e self swab however subject stat es COVID testing already compl eted	New Information
Nov-10-2020 08:56:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-10-2020 08:56:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Subject instructed to collect hom e self swab	Transcription Error
Nov-10-2020 08:56:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Subject instructed to collect a ho me self swab. Subject agreed to collect in day or so. Date unkno wn when subject will collect swa b	Transcription Error
Nov-10-2020 08:52:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Entered text has either a carriage return (line break) or extra spaces at the end of the text or

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/05/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - 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: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

				between words. Please correct by removing all data in the field and re-enter without adding extra spaces or using enter or tab keys.
Nov-10-2020 08:52:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Instructed subject to collect home self swab. Subject agreed, but unwilling to collect today. Subject will notify site when swab collected	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-20-2020 16:06:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: CV17734	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-20-2020 16:06:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CV17734	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/05/2020

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: 10951101

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
Nov-10-2020 08:52:53 (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
Nov-10-2020 08:52:53 (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
Nov-10-2020 08:52:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Nov-10-2020 09:24:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> subject instructed to collect home self swab however subject states COVID testing completed in hosp ital	New Information
Nov-10-2020 08:56:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-10-2020 08:56:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> home self swab will be collected	Transcription Error
Nov-10-2020 08:52:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Entered text has either a carriage return (line break) or extra spaces at the

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Nov/05/2020

**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:** 10951101

**Subject Initials:** ---

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

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

				end of the text or between words. Please correct by removing all data in the field and re-enter without adding extra spaces or using enter or tab keys.
Nov-10-2020 08:52:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Subject to collect home self swab	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/05/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

**1.a**

Date	Location	User	Value	Reason
Nov-10-2020 08:54:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> SPECIALIST <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

**1.a Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Nov-10-2020 08:54:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SPECIALIST	Initial Entry

**1.a Occurrence of Visits or Contacts:**

Date	Location	User	Value	Reason
Nov-10-2020 08:54:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**1.b**

Date	Location	User	Value	Reason
Nov-10-2020 08:54:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERGENCY ROOM <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History  
on Nov/05/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1095**Site Name:** (1095) Tekton Research**Subject No:** 10951101**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39***1.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-10-2020 08:54:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EMERGENCY ROOM	Initial Entry

***1.b Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Nov-10-2020 08:54:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.c***

Date	Location	User	Value	Reason
Nov-10-2020 08:54:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> PRIMARY CARE PHYSICIAN <b>Occurrence of Visits or Contacts:</b> YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

***1.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-10-2020 08:54:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PRIMARY CARE PHYSICIAN	Initial Entry

***1.c Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Nov-10-2020 08:54:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/05/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

*1.d*

Date	Location	User	Value	Reason
Nov-10-2020 08:54:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> URGENT CARE <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

*1.d Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Nov-10-2020 08:54:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> URGENT CARE	Initial Entry

*1.d Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Nov-10-2020 08:54:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*1.e*

Date	Location	User	Value	Reason
Nov-10-2020 08:54:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> TELEPHONE CONSULTATION <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History  
on Nov/05/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1095**Site Name:** (1095) Tekton Research**Subject No:** 10951101**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-10-2020 08:54:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> TELEPHONE CONSULTATION	Initial Entry

***1.e Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Nov-10-2020 08:54:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.f***

Date	Location	User	Value	Reason
Nov-10-2020 08:54:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OTH R <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

***1.f Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-10-2020 08:54:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

***1.f Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Nov-10-2020 08:54:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-10-2020 08:54:01 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History  
on Nov/05/2020

**Form Version:** 10-Oct-2020 15:59

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

Time (US & Canada)	(b) (4), (b) (6)	Has the subject been in intensive care due to potential COVID-19 illness?	
		NO	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS - Audit Trail  
on Nov/05/2020

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

**Form Status:**

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-10-2020 08:54:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HOSPITALIZATION DETAILS - eCRF Audit Trail History on Nov/05/2020

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Hospitalization Category:

Date	Location	User	Value	Reason
Nov-10-2020 08:54:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> HOSPITALIZATION STATUS	Initial Entry

2. Hospitalization Term:

Date	Location	User	Value	Reason
Nov-10-2020 08:54:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HOSPITAL	Initial Entry

3. Admission Date:

Date	Location	User	Value	Reason
Nov-12-2020 18:21:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-12-2020 17:20:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Participant was hospitalized but not for COVID!!! Participant reported SOB and a covid illness visit was started. Participant was then diagnosed with a pulmonary embolism which is what resulted in the hospitalization. Not a covid diagnosis
Nov-11-2020 13:36:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLIQUEY: Hospitalization: Subject had COVID-19 Illness and was hospitalized. Please enter on the CRF form any available

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS - eCRF Audit Trail History  
on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

				information (vital signs, pulse oxymet, respiratory treatment, lab results, imaging...). Please make every effort to obtain information
Nov-11-2020 09:04:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	CLIQUEY: Hospitalization: Subject had COVID-19 Illness and was hospitalized. Please enter on the CRF form any available information (vital signs, pulse oxymet, respiratory treatment, lab results, imaging...). Please make every effort to obtain information
Nov-10-2020 08:54:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/5/2020	Initial Entry

**4. Ongoing?**

Date	Location	User	Value	Reason
Nov-10-2020 08:54:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Discharge Date: Nov/7/2020	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: RESPIRATORY TREATMENT - eCRF Audit Trail History on Nov/05/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Nov-10-2020 08:57:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Nov-10-2020 08:57:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Nov-10-2020 08:57:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Nov-10-2020 08:57:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Nov-10-2020 08:57:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Nov-10-2020 08:57:19 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History  
on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

Time (US & Canada)	(b) (4), (b) (6)
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090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - eCRF Audit Trail History on Nov/05/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Category of Clinical Event:

Date	Location	User	Value	Reason
Nov-10-2020 08:58:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID-19 ILLNESS	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Nov-10-2020 08:58:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Respiratory Illness Diagnosis:</i>  Pulmonary embolism  Date of Diagnosis:  Nov/5/2020	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-10-2020 08:58:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - SEVERE - eCRF Audit Trail History on Nov/05/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Nov-10-2020 08:58:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Subcategory of Clinical Event:**

Date	Location	User	Value	Reason
Nov-10-2020 08:58:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Was a diagnosis obtained?**

Date	Location	User	Value	Reason
Nov-10-2020 08:58:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Toxicity Grade:**

Date	Location	User	Value	Reason
Nov-10-2020 08:58:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/05/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[Back to Form](#)

**1. Lab Panel:**

Date	Location	User	Value	Reason
Nov-10-2020 08:58:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Nov-10-2020 08:58:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Nov-10-2020 08:58:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Nov-10-2020 08:58:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-10-2020 08:58:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Unkn wn <b>Test::</b> Unkn wn <b>Result::</b> Unkn wn	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/05/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

			<b>Not Done::</b>	Unkno wn
			<b>Lab Normal Range:</b>	Unkno wn

5.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-10-2020 08:58:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Nov-10-2020 08:58:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Nov-10-2020 08:58:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Nov-10-2020 08:58:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Nov-10-2020 08:58:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

5.b

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/05/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Nov-10-2020 08:58:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Unkno wn <b>Test::</b> Unkno wn <b>Result::</b> Unkno wn <b>Not Done::</b> Unkno wn <b>Lab Normal Range:</b> Unkno wn	Initial Entry



Header Text: c4591001

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

5.b Sponsor ID:

Date	Location	User	Value	Reason
Nov-10-2020 08:58:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Nov-10-2020 08:58:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Nov-10-2020 08:58:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
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5.b LNMT

Date	Location	User	Value	Reason
Nov-10-2020 08:58:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-10-2020 08:58:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sponsor-Defined Identifier: Unknwn	Initial Entry

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**Header Text:** c4591001

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

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5.c Test:

Date	Location	User	Value	Reason
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5.c Result:

Date	Location	User	Value	Reason
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5.c Not Done:

Date	Location	User	Value	Reason
Nov-10-2020 08:58:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Nov-10-2020 08:58:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-10-2020 08:58:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sponsor-Defined Identifier: Unknwn	Initial Entry

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			<b>Lab Normal Range:</b>	Unkno wn	

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5.d Sponsor ID:

Date	Location	User	Value	Reason
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5.d Not Done:

Date	Location	User	Value	Reason
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5.d LNMT

Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
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**Header Text:** c4591001

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**Site No:** 1095

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

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

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

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5.e Not Done:

Date	Location	User	Value	Reason
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5.e LNMT

Date	Location	User	Value	Reason
Nov-10-2020 08:58:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

5.f

Date	Location	User	Value	Reason
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**Site No:** 1095

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**Subject No:** 10951101

**Subject Initials:** ---

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

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

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5.f Sponsor ID:

Date	Location	User	Value	Reason
Nov-10-2020 08:58:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

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Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
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Nov-10-2020 08:58:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

5.g

Date	Location	User	Value	Reason
Nov-10-2020 08:58:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sponsor-Defined Identifier: Unknwn	Initial Entry

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

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

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Date	Location	User	Value	Reason
Nov-10-2020 08:58:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Nov-10-2020 08:58:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

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Date	Location	User	Value	Reason
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5.g LNMT

Date	Location	User	Value	Reason
Nov-10-2020 08:58:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/05/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Nov-10-2020 08:59:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
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3. Collection Date:

Date	Location	User	Value	Reason
Nov-10-2020 08:59:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Nov-10-2020 08:59:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-10-2020 08:59:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Unkn wn <b>Test::</b> Unkn wn <b>Result::</b> Unkn wn	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

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			<b>Not Done::</b>	Unkno wn
			<b>Lab Normal Range:</b>	Unkno wn

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Date	Location	User	Value	Reason
Nov-10-2020 08:59:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

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5.c Sponsor ID:

Date	Location	User	Value	Reason
Nov-10-2020 08:59:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Nov-10-2020 08:59:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Nov-10-2020 08:59:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Nov-10-2020 08:59:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Nov-10-2020 08:59:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

5.d

Date	Location	User	Value	Reason
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090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/05/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

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5.d LNMT

Date	Location	User	Value	Reason
Nov-10-2020 08:59:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

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Date	Location	User	Value	Reason
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5.e Not Done:

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5.e LNMT

Date	Location	User	Value	Reason
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5.f

Date	Location	User	Value	Reason
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**Generated Time (GMT):** 29-Mar-2021 10:39

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			<b>Lab Normal Range:</b>	Unkno wn	

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5.g

Date	Location	User	Value	Reason
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			<b>Lab Normal Range:</b>	Unkno wn	



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Date	Location	User	Value	Reason
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**Generated Time (GMT):** 29-Mar-2021 10:39

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			<b>Lab Normal Range:</b>	Unkno wn	

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

[Back to Form](#)

**5.i Sponsor ID:**

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**5.j**

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Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Nov/05/2020

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Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Nov-10-2020 09:04:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry
Nov-10-2020 09:02:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-10-2020 09:04:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> Not Done <b>Systolic::</b> Unknown <b>Diastolic::</b> Unknown <b>Respiratory Rate in respirations/minute:</b> Unknown <b>Heart Rate in beats/minute:</b> Unknown	Initial Entry
Nov-10-2020 09:02:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> Not Done <b>Systolic::</b> Not Done <b>Diastolic::</b> Not Done <b>Respiratory Rate in respirations/minute:</b> Not Done <b>Heart Rate in beats/minute:</b> Not Done	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
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090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)



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Nov-10-2020 09:02:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
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**2.a Systolic:**

Date	Location	User	Value	Reason
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Nov-10-2020 09:02:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a Diastolic:**

Date	Location	User	Value	Reason
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Nov-10-2020 09:02:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a Respiratory Rate in respirations/minute:**

Date	Location	User	Value	Reason
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Nov-10-2020 09:02:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a Heart Rate in beats/minute:**

Date	Location	User	Value	Reason
Nov-10-2020 09:04:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

Nov-10-2020 09:02:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/05/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Nov-10-2020 09:03:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-10-2020 09:03:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> Unknown <b>Oxygen Saturation:</b> Unknown	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-10-2020 09:03:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Nov-10-2020 09:03:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History on Nov/05/2020

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[Back to Form](#)

**1. Date Time of Assessment:**

Date	Location	User	Value	Reason
Nov-10-2020 09:04:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

**2. Arterial Blood Gases PaO2 (mmHg):**

Date	Location	User	Value	Reason
Nov-10-2020 09:04:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

**3. FiO2 (Fraction of Inhaled Oxygen):**

Date	Location	User	Value	Reason
Nov-10-2020 09:04:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/05/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. What is the medication identifier?

Date	Location	User	Value	Reason
Nov-10-2020 09:04:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Nov-10-2020 09:04:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Nov-10-2020 09:04:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Nov-10-2020 09:04:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Nov-10-2020 09:04:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

6. Ongoing?

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Nov/05/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF  
Audit Trail History

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Nov-10-2020 09:04:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** IMAGING - Audit Trail  
on Nov/05/2020

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

**Form Status:**

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-10-2020 09:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: IMAGING - eCRF Audit Trail History  
on Nov/05/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

**1. Date of Assessment:**

Date	Location	User	Value	Reason
Nov-10-2020 09:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/5/2020	Initial Entry

**2. Location of Assessment:**

Date	Location	User	Value	Reason
Nov-10-2020 09:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHEST	Initial Entry

**3. Type of Imaging Exam:**

Date	Location	User	Value	Reason
Nov-10-2020 09:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> X-RAY	Initial Entry

**4. Assessment:**

Date	Location	User	Value	Reason
Nov-10-2020 09:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNKNOWN	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (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:** 10951101

**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
Sep-30-2020 14:47:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/28/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Sep-30-2020 14:47:48 (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
Sep-30-2020 14:47:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1095

**Subject No:** 10951101

**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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-10-2020 08:40:28 (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: 10951101

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

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Nov-10-2020 08:40:28 (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
Nov-10-2020 08:40:28 (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
Nov-10-2020 08:40:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Pulmonary Embolism	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Nov-10-2020 08:40:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/30/2020 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Nov-10-2020 08:40:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Nov/7/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
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090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

Nov-10-2020 08:40:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry
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**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

**Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).**

Date	Location	User	Value	Reason
Nov-12-2020 12:20:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-12-2020 10:03:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	This has been submitted
Nov-11-2020 06:32:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON: Pulmonary Embolism(Onset date:30Oct2020) is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF
Nov-11-2020 06:32:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query can be addressed internally
Nov-10-2020 08:40:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Pulmonary Embolism: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1095

Subject No: 10951101

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

Nov-10-2020 08:40:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b> YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	Initial Entry
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**8. Is this adverse event the result of a study Medication Error?**

*If Yes, record the type of medication error on the Medication Error Log.*

Date	Location	User	Value	Reason
Nov-10-2020 08:40:28 (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
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090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1095

Subject No: 10951101

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

Nov-10-2020 08:40:28 (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  <i>If Other, specify:</i>  HRT and prolonged immobilization	Initial Entry
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-10-2020 08:40:28 (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
Dec-01-2020 17:53:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-23-2020 14:05:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	SAE report does report medication in the narrative. Medication for Eliquis.
Nov-19-2020 12:49:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL Con Med for SAE is reported; however SAE report does not specify medical treatment for PE (only Rx discussed is levofloxacin). Please review and update as required, in the appropriate location
Nov-10-2020 08:40:28 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951101

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-10-2020 08:40:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-10-2020 08:40:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-10-2020 08:40:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Nov-12-2020 12:17:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 2020447041	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1095

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

**Subject No:** 10951101

**Subject Initials:** ---

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

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

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Jan-13-2021 09:18:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/8/2021	Initial Entry



**Header Text:** c4591001

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

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

**Site No:** 1095

**Subject No:** 10951101

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

**Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail  
History

**Form Status:** Data Complete, Frozen

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

**Subject Initials:** ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Mar-01-2021 15:20:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is willing to return fo r Vaccination 3 Participant is:  eligible and NOT confirmed t o have received only placebo at Vaccination 1/2	Transcription Error
Jan-13-2021 09:19:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is NOT willing to ret urn for Vaccination 3 OR otherw ise not eligible	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951101

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

[Back to Form](#)

**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Feb-26-2021 15:30:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/8/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Mar-01-2021 22:27:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-01-2021 15:21:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Mar-01-2021 15:16:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rivkah Rosen (b) (4)	Query 1: Reissued: Opened	DM: Form has been unfrozen. Please update the data per prior query. Thank you.
Mar-01-2021 09:41:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Please unfreeze and re-query.
Feb-26-2021 23:54:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7482191;Primary Reason for Unblinding is "ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION", but

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1095

**Subject No:** 10951101

**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

				"Participant is willing to return for Vaccination 3" is not selected in the Further Vaccination Confirmation CRF. Please review and update as appropriate.
Feb-26-2021 15:30:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1095

**Subject No:** 10951101

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

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

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

[Back to Form](#)

**1. Subject Status**

Date	Location	User	Value	Reason
Sep-30-2020 14:47:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Aug-07-2020 19:03:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Aug-07-2020 18:37:51 (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
Sep-30-2020 14:47:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/28/2020	Initial Entry
Aug-07-2020 19:03:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/7/2020	Initial Entry
Aug-07-2020 18:37:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/7/2020	Initial Entry

090177e196ae2fb2\Final\Final On: 01-Apr-2021 03:48 (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:** 10951101

**Subject Initials:** ---

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

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

[Back to Form](#)

*1. Casebook Signature*

Date	Location	User	Value	Reason
Sep-22-2020 17:04:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry