

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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[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: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/14/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: DEMOGRAPHY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10181159]
2.	Birth Date:	(b) (6) 1967
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:	

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Aug/14/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Aug/14/2020
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: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Obstructive breathing due to deviated septum]
	Start Date:	(b) (6)/1967
	Ongoing:	NO End Date: UNK/UNK/2017
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Rhinoplasty]
	Start Date:	UNK/UNK/2008
	Ongoing:	NO End Date: UNK/UNK/2008
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Rhinoplasty]
	Start Date:	UNK/UNK/2017
	Ongoing:	NO End Date: UNK/UNK/2017

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[right shoulder dislocation]
	Start Date:	UNK/UNK/2014
	Ongoing:	NO End Date: UNK/UNK/2014
1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Right Shoulder Repair]
	Start Date:	UNK/UNK/2014
	Ongoing:	NO End Date: UNK/UNK/2014
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Breast augmentation]
	Start Date:	UNK/UNK/2010
	Ongoing:	NO End Date: UNK/UNK/2010
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Fibrocystic Breast Disease]
	Start Date:	UNK/UNK/1993
	Ongoing:	NO End Date: UNK/UNK/1993

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1 h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Migraines once or twice a month]
	Start Date:	UNK/UNK/2008
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Vitamin D deficiency]
	Start Date:	UNK/UNK/2013
	Ongoing:	NO End Date: UNK/UNK/2014
1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[benign cyst removed]
	Start Date:	UNK/UNK/1993
	Ongoing:	NO End Date: UNK/UNK/2009
1 k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Occipital Neuralgia R>L]
	Start Date:	UNK/UNK/2014
	Ongoing:	YES

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.1	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Chronic Neck Pain]
	Start Date:	UNK/UNK/2008
	Ongoing:	YES
1.2	Line/MH Number:	[13]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Vitamin B12 Deficiency]
	Start Date:	UNK/UNK/2009
	Ongoing:	YES

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Vital Signs

1.	Date:	Aug/14/2020
2.	Weight:	[137.0]
3.	Unit:	LB
4.	Height:	[69.5]
5.	Unit:	in
6.	Body Mass Index:	[19.9]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[95.5]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/14/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Aug/14/2020
2.	Randomization Number:	[50249]
3.	Randomization Group:	[]

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/14/2020
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	[BP69J3]
5.b	Sample ID	[BP69J4]
5.c	Sample ID	[BP69J5]
5.d	Sample ID	[BPG680]
5.e	Sample ID	[BPG681]

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/14/2020
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	[BP69HX]
-----	-----------	----------

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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/14/2020 11:33
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

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/4/2020
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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[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

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/4/2020
----	-------	------------

Vital Signs Details

2.a	Record Identifier:	1	
	Temperature:	[95.2]	Comments
	Unit:	F	Comments
	Temperature Location:	ORAL CAVITY	Comments

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Lab Urinalysis

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

Lab Result

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

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/4/2020
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	[BHTYD9]
-----	-----------	----------

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/4/2020 16:07
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/7/2020
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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/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	[BP9FVK]
5.b	Sample ID	[BP9FVL]
5.c	Sample ID	[BLB1PG]
5.d	Sample ID	[BLB1PH]

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Mar/1/2021
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	[BR1387]
5.b	Sample ID	[BR1388]
5.c	Sample ID	[BS7GRN]
5.d	Sample ID	[BS7GRP]

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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	[]
----	-----------	-----

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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	[]
----	-----------	-----

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Signs and Symptoms

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

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

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

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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	[]
----	-----------	-----

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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	[]
----	-----------	-----

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

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

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52 **Form Status:** Not Started

Site No: 1018 **Site Name:** (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 04:44

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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	[]
----	-----------	-----

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Unplanned Assessments

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Oct/7/2020
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: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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	[]
----	-----------	-----

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Right Leg Paresthesia	Oct/20/2020 UNK: UNK	YES	Repeating Pages

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)
[Form Comments](#)
[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)	[Right Leg Paresthesia]
4.	Start Date Time:	Oct/20/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? NO Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event YES
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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?:	RECOVERING/RESOLVING
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020447492]

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[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	[]

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[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:	//

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[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?	

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[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?	

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Vital Signs

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

Vital Signs Details

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

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001**Visit:** Unplanned Vaccination - Unscheduled**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Version:** 20-Feb-2021 02:14**Form Status:** Not Started**Site No:** 1018**Site Name:** (1018) Texas Center For Drug Development, Inc.**Subject No:** 10181159**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44**Lab Urinalysis**

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

Lab Result

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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?	

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form Version: 14-Jan-2021 02:29

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE

Form Status: Not Started

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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	[]
----	-----------	-----

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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	[]
----	-----------	-----

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Dec/16/2020
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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[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
----	---	--

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Dec/16/2020
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Withdrawal Of Consent

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

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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 Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/7/2020

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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[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: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-14-2020 12:41:33 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
2.a	Sep-04-2020 16:08:46 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	per source - not clinically significant

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
2.a	Sep-04-2020 16:08:46 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	per source - not clinically significant

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
2.a	Sep-04-2020 16:08:46 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	per source - not clinically significant

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Comments

Form Status: Data Complete, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-22-2021 16:41:24 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Vitamin b12 deficiency was deleted from medical history after consolation with patient. Patient denies having b12 deficiency or received treatment.

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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[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
William Fernandez	N/A	Mar-02-2021 23:11:18 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

(b) (6)	Approved	Jan-25-2021 21:02:26 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
---------	----------	---	------	--------

Affidavit:

By my dated signature below, I, (b) (6), verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

(b) (6)	N/A	Jan-06-2021 13:46:41 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
---------	-----	---	--	-----------------------------------

Affidavit:

N/A

(b) (6)	Approved	Nov-18-2020 11:28:57 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
---------	----------	---	------	--------

Affidavit:

By my dated signature below, I, (b) (6), 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.

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

(b) (6)	N/A	Nov-17-2020 19:59:55 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
---------	-----	---	--	-----------------------------------

Affidavit:

N/A

(b) (6)	Approved	Nov-13-2020 12:09:49 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
---------	----------	---	------	--------

Affidavit:

By my dated signature below, I, (b) (6), 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-12-2020 11:13:02 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
---------	-----	---	--	-----------------------------------

Affidavit:

N/A

(b) (6)	Approved	Oct-12-2020 19:59:35 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
---------	----------	---	------	--------

Affidavit:

By my dated signature below, I, (b) (6), 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.

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-14-2020 12:40:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 12:40:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

I. Consent Was:

Date	Location	User	Value	Reason
Aug-14-2020 12:40:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Aug/14/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Aug-14-2020 12:40:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10181159	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-14-2020 12:40:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1967	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-14-2020 12:41:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-14-2020 12:41:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 12:41:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Aug-14-2020 12:41:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/14/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-14-2020 12:41:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/14/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-14-2020 12:41:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-14-2020 12:41:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

I.a

Date	Location	User	Value	Reason
Aug-14-2020 12:42:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 1 Number: Medical History Term: Obstructive breathing due to deviated septum Start Date: (b) (6)/1967 : Ongoing: NO End Date: UNK/UNK/2017	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-14-2020 12:42:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 12:42:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Obstructive breathing due to deviated septum	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Aug-14-2020 12:42:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: (b) (6) 1967	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Aug-14-2020 12:42:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2017	Initial Entry
---	-----------------	---------------------	---	---------------

I.b

Date	Location	User	Value	Reason
Aug-14-2020 12:43:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: Rhinoplasty Start Date: UNK/UNK/2008 Ongoing: NO End Date: UNK/UNK/2008	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

I.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-14-2020 12:43:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 12:43:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Rhinoplasty	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Aug-14-2020 12:43:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2008	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Aug-14-2020 12:43:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2008	Initial Entry

I.c

Date	Location	User	Value	Reason
Aug-14-2020 12:44:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 er: Medical History Rhinoplasty Term: Start Date: UNK/UNK/2017	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

			Ongoing:	NO	
				End Date:	
				UNK/UNK/2017	

I.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-14-2020 12:44:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 12:44:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Rhinoplasty	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-14-2020 12:44:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2017	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-14-2020 12:44:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2017	Initial Entry

I.d

Date	Location	User	Value	Reason
Aug-17-2020 12:01:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Nu 4 mber:	Transcription Error

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

			Medical History Term: right shoulder dislocation Start Date: UNK/UNK/2014 Ongoing: NO End Date: UNK/UNK/2014	
Aug-14-2020 17:30:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 4 Medical History Term: Right Shoulder Dislocation Start Date: UNK/UNK/2014 Ongoing: NO End Date: UNK/UNK/2014	Transcription Error
Aug-14-2020 12:44:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: Right Shoulder Dislocation due to fall Start Date: UNK/UNK/2014 Ongoing: NO End Date: UNK/UNK/2014	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-14-2020 12:44:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Jan-22-2021 15:53:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Jan-22-2021 15:26:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Changed data per query
Jan-22-2021 12:45:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued: Opened	Clinical / Unfrozen: On review of SAE report for Paresthesia, Med Hx of Neck Pain was mentioned, yet it does not appear in Med Hx CRF. Please review for clinical relevance to safety event and update Med Hx log CRF if appropriate
Jan-22-2021 10:39:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Please unfreeze Hx CRF

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Dec-06-2020 12:42:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Re issued:Open ed	Clinical On review of SAE report for Paresthesia, Med Hx of Neck Pain was mentioned, yet it does not appear in Med Hx CRF. Please review for clinical relevance to safety event and update Med Hx log CRF if appropriate.
Dec-03-2020 12:13:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: An swered	Waiting on PI review.
Nov-24-2020 07:39:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Op ened	Clinical On review of SAE report for Paresthesia, Med Hx of Neck Pain was mentioned, yet it does not appear in Med Hx CRF. Please review for clinical relevance to safety event and update Med Hx log CRF if appropriate.
Aug-18-2020 02:37:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Cl osed	Response satisfies query
Aug-17-2020 12:01:00 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: An swered	Transcription Error

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Central Time (US & Canada)				
Aug-17-2020 12:01:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : right should er dislocation	Transcription Error
Aug-17-2020 11:46:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM QUERY: A trailing space is identified. To avoid processing errors, please remove the identified character by deleting the entry and re-entering the data (without using copy and paste).
Aug-14-2020 18:35:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Aug-14-2020 17:30:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Aug-14-2020 17:30:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Right Shoulder Dislocation	Transcription Error
Aug-14-2020 14:35:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Multiple concepts in the term RIGHT SHOULDER DISLOCATION DUE TO FALL.

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

				Split the term into RIGHT SHOULDER DISLOCATION and FALL and submit separately. Thank you.
Aug-14-2020 12:44:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Right Shoulder Dislocation due to fall	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Aug-14-2020 12:44:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2014	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Aug-14-2020 12:44:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2014	Initial Entry

I.e

Date	Location	User	Value	Reason
Aug-14-2020 12:45:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: Right Shoulder Repair Start Date: UNK/UNK/2014	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

			Ongoing: NO End Date: UNK/UNK/ 2014	
--	--	--	---	--

I.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-14-2020 12:45:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 12:45:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Right Shoulder Repair	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Aug-14-2020 12:45:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2014	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Aug-14-2020 12:45:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2014	Initial Entry

I.f

Date	Location	User	Value	Reason
Aug-14-2020 12:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numb 6 er:	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

			Medical History Term: Breast augmentation Start Date: UNK/UNK/2010 Ongoing: NO End Date: UNK/UNK/2010	
--	--	--	---	--

I.f Line/MH Number:

Date	Location	User	Value	Reason
Aug-14-2020 12:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 12:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Breast augmentation	Initial Entry

I.f Start Date:

Date	Location	User	Value	Reason
Aug-14-2020 12:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

I.f Ongoing:

Date	Location	User	Value	Reason
Aug-14-2020 12:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2010	Initial Entry

I.g

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Aug-17-2020 08:37:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 7 Medical History Term: Fibrocystic Breast Disease Start Date: UNK/UNK/1993 Ongoing: NO End Date: UNK/UNK/1993	Clarification
Aug-14-2020 17:29:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 7 Medical History Term: Fibrocystic Breast Disease, benign cyst removed Start Date: UNK/UNK/1993 Ongoing: NO End Date: UNK/UNK/1993	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

I.g Line/MH Number:

Date	Location	User	Value	Reason
Aug-14-2020 17:29:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

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

Date	Location	User	Value	Reason
Aug-17-2020 09:49:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Aug-17-2020 08:37:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Clarification
Aug-17-2020 08:37:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Fibrocystic Breast Disease	Clarification
Aug-14-2020 20:10:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Multiple concepts in the term FIBROCYSTIC BREAST DISEASE, BENIGN CYST REMOVED. Split the term into FIBROCYSTIC BREAST DISEASE and BENIGN CYST REMOVED and submit

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

				separately. Thank you.
Aug-14-2020 17:29:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Fibrocystic Breast Disea se, benign c yst removed	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Aug-14-2020 17:29:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1993	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Aug-14-2020 17:29:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1993	Initial Entry

I.h

Date	Location	User	Value	Reason
Aug-17-2020 09:44:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH N 8 umber: Medical His Migraines once o tory Term: r twice a month Start Date: UNK/UNK/2008 Ongoing: YES	Transcription Error
Aug-14-2020 17:29:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numb 8 er: Medical History Migraines Term: Start Date: UNK/UNK/ 2008	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

			Ongoing:	YES	
--	--	--	-----------------	-----	--

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

I.h Line/MH Number:

Date	Location	User	Value	Reason
Aug-14-2020 17:29:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Jan-22-2021 15:53:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-22-2021 15:27:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Jan-22-2021 12:46:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Clinical Unfrozen: On review of SAE report for Paresthesia, Med Hx of R>L occipital neuralgia was mentioned, yet it does not appear in Med Hx CRF. Please review for clinical relevance to safety event and update Med Hx log CRF if appropriate.
Jan-22-2021 10:38:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Please unfreeze Hx CRF
Dec-06-2020 12:43:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Clinical On review of SAE report for Paresthesia, Med Hx of R>L occipital neuralgia was mentioned, yet it does not appear in Med Hx CRF. Please review for

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

				clinical relevance to safety event and update Med Hx log CRF if appropriate.
Dec-03-2020 12:13:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Waiting on PI review.
Nov-24-2020 07:38:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical On review of SAE report for Paresthesia, Med Hx of R>L occipital neuralgia was mentioned, yet it does not appear in Med Hx CRF. Please review for clinical relevance to safety event and update Med Hx log CRF if appropriate.
Aug-17-2020 09:44:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Migraines once or twice a month	Transcription Error
Aug-14-2020 17:29:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Migraines	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Aug-14-2020 17:29:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2008	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Aug-14-2020 17:29:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

I.i

Date	Location	User	Value	Reason
Aug-14-2020 17:30:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 9 Medical History Term: Vitamin D deficiency Start Date: UNK/UNK/2013 Ongoing: NO End Date: UNK/UNK/2014	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.i Line/MH Number:

Date	Location	User	Value	Reason
Aug-14-2020 17:30:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

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

Date	Location	User	Value	Reason
Jan-22-2021 20:56:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-22-2021 16:01:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject did not have Vit B-12, SAE report is being amended and will be updated
Jan-22-2021 15:55:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Clinical Vit B12 deficiency was added as a Med Hx condition, but then crossed out. Please clarify if subject never had Vit B12 deficiency (then, remove this history from SAE). Or re-add if subj did have Vit B12 def on study day 1
Jan-22-2021 15:27:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Jan-22-2021 12:45:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Clinical Unfrozen: On review of SAE for Paresthesia, Med Hx of Vitamin B12 deficiency was reported, yet is not on Med Hx CRF. Is subj on B12

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

				injections/was subject assessed for Pernicious anemia? Please review, update Med Hx and SAE if appropriate
Jan-22-2021 09:01:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Please unfreeze medical Hx so it can be updated
Dec-06-2020 12:41:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Event of osteopenia reported after V3
Dec-06-2020 12:40:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Clinical On review of SAE report for Paresthesia, Med Hx of Vitamin B12 deficiency was reported, yet is not on Med Hx CRF. Is subj on B12 injections/was subject assessed for Pernicious anemia? Please review, update Med Hx and SAE if appropriate
Dec-03-2020 12:13:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Waiting on PI review.
Dec-03-2020 12:13:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Waiting on PI review.
Nov-24-2020 07:39:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical On review of SAE report for Paresthesia, Med Hx of Osteopena was mentioned, yet it does not appear in Med Hx CRF. Please review for clinical relevance to

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

				safety event and update Med Hx log CRF if appropriate.
Nov-24-2020 07:36:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical On review of SAE report for Paresthesia, Med Hx of Vitamin B12 deficiency was reported, yet is not on Med Hx CRF. Is subj on B12 injections/was subject assessed for Pernicious anemia? Please review, update Med Hx and SAE if appropriate
Aug-14-2020 17:30:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Vitamin D deficiency	Initial Entry

L.i Start Date:

Date	Location	User	Value	Reason
Aug-14-2020 17:30:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2013	Initial Entry

L.i Ongoing:

Date	Location	User	Value	Reason
Aug-14-2020 17:30:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2014	Initial Entry

L.j

Date	Location	User	Value	Reason
Jan-22-2021 15:26:10 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Num 10	Transcription Error

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)		(b) (4), (b) (6)	ber: Medical History Term: benign cyst removed Start Date: UNK/UNK/1993 Ongoing: NO End Date: UNK/UNK/2009	
Aug-17-2020 08:39:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 10 ber: Medical History Term: benign cyst removed Start Date: UNK/UNK/1993 Ongoing: NO End Date: UNK/UNK/1993	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1018**Subject No:** 10181159**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1018) Texas Center For Drug Development, Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44***1.j Line/MH Number:***

Date	Location	User	Value	Reason
Aug-17-2020 08:39:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

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

Date	Location	User	Value	Reason
Aug-17-2020 08:39:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: benign cyst removed	Initial Entry

1.j Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 08:39:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1993	Initial Entry

1.j Ongoing:

Date	Location	User	Value	Reason
Jan-22-2021 15:26:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2009	Transcription Error
Aug-17-2020 08:39:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1993	Initial Entry

1.k

Date	Location	User	Value	Reason
Jan-22-2021 15:22:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 11 ber:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

			Medical History Term: Occipital Neuralgia R>L Start Date: UNK/UNK/2014 Ongoing: YES
--	--	--	--

1.k Line/MH Number:

Date	Location	User	Value	Reason
Jan-22-2021 15:22:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11	Initial Entry

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

Date	Location	User	Value	Reason
Jan-22-2021 15:22:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Occipital Neuralgia R>L	Initial Entry

1.k Start Date:

Date	Location	User	Value	Reason
Jan-22-2021 15:22:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2014	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1.k Ongoing:

Date	Location	User	Value	Reason
Jan-22-2021 15:22:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.l

Date	Location	User	Value	Reason
Jan-22-2021 15:24:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 12 r: Medical History: Chronic Neck Term: Pain Start Date: UNK/UNK/2 008 Ongoing: YES	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

1.1 Line/MH Number:

Date	Location	User	Value	Reason
Jan-22-2021 15:24:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12	Initial Entry

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

Date	Location	User	Value	Reason
Jan-22-2021 15:24:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Chronic Neck Pain	Initial Entry

1.1 Start Date:

Date	Location	User	Value	Reason
Jan-22-2021 15:24:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2008	Initial Entry

1.1 Ongoing:

Date	Location	User	Value	Reason
Jan-22-2021 15:24:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.m

Date	Location	User	Value	Reason
Jan-22-2021 15:48:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Num 13 ber: Medical Histor Vitamin B12 D y Term: efficiency Start Date: UNK/UNK/20 09 Ongoing: YES	Spoke with subject directly, she denies any history and treatment for Vitamin B12 Deficiency (DELETED)
Jan-22-2021 15:25:40 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 13	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)			ber: Medical History Term: Vitamin B12 D efficiency Start Date: UNK/UNK/2009 Ongoing: YES	
--------------------	--	--	--	--

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

I.m Line/MH Number:

Date	Location	User	Value	Reason
Jan-22-2021 15:48:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 13	Spoke with subject directly, she denies any history and treatment for Vitamin B12 Deficiency (DELETED)
Jan-22-2021 15:25:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 13	Initial Entry

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

Date	Location	User	Value	Reason
Jan-22-2021 15:48:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Vitamin B12 Deficiency	Spoke with subject directly, she denies any history and treatment for Vitamin B12 Deficiency (DELETED)
Jan-22-2021 15:25:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Vitamin B12 Deficiency	Initial Entry

I.m Start Date:

Date	Location	User	Value	Reason
Jan-22-2021 15:48:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/2009	Spoke with subject directly, she denies any history and treatment for Vitamin B12 Deficiency (DELETED)
Jan-22-2021 15:25:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/2009	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

I.m Ongoing:

Date	Location	User	Value	Reason
Jan-22-2021 15:48:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Spoke with subject directly, she denies any history and treatment for Vitamin B12 Deficiency (DELETED)
Jan-22-2021 15:25:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Aug-14-2020 12:53:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/14/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-14-2020 12:53:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 137.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-14-2020 12:53:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-14-2020 12:53:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 69.5	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-14-2020 12:53:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-14-2020 12:53:32	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-06:00) Central Time (US & Canada)		(autocalc)	19.9	
--	--	------------	------	--

7.a

Date	Location	User	Value	Reason
Aug-14-2020 12:53:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier 1 : Temperature: 95.5 Temperature Unit: Temperature Location: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-14-2020 12:53:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-17-2020 07:37:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed by DM: AT.
Aug-14-2020 12:54:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	per source
Aug-14-2020 12:53:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Temperature 95.5 F is outside of Normal Range 97 - 99.5 F.
Aug-14-2020 12:53:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 95.5	Initial Entry

7.a Unit:

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Aug-14-2020 12:53:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-14-2020 12:53:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> ORAL CAVITY	Initial Entry

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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Aug-14-2020 12:54:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-14-2020 12:54:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-18-2020 09:27:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-18-2020 09:27:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of collection is reported, but result is missing. Please review and update as appropriate.
Aug-14-2020 12:54:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/14/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-14-2020 12:54:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Aug-14-2020 12:54:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-18-2020 09:27:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Sponsor-Defined Identifier: Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::	Initial Entry
Aug-18-2020 09:27:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Sponsor-Defined Identifier: Test:: Choriogonadotropin Beta_PX113 Result:: Not Done::	Clarification, Test was performed
Aug-14-2020 12:54:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Sponsor-Defined Identifier: Test:: Choriogonadotropin Beta_PX113 Result:: Not Done:: NOT DONE	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-18-2020 09:27:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 113	Initial Entry
Aug-18-2020 09:27:20 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Clarification, Test was performed

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)				
Aug-14-2020 12:54:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-14-2020 12:54:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX11 3	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-18-2020 09:27:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Aug-19-2020 21:14:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-18-2020 09:27:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Clarification, Test was performed
Aug-18-2020 09:27:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Clarification, Test was performed
Aug-17-2020 20:26:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	please can you confirm why a pregnancy test was not done for this subject? There is nothing in her medhx to indicate she is not a woman of child bearing

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

				potential? Thanks
Aug-14-2020 12:54:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NOT DONE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Randomization Date :

Date	Location	User	Value	Reason
Aug-14-2020 12:55:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/14/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-14-2020 12:55:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 50249	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Aug-14-2020 12:55:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-14-2020 12:55:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-14-2020 12:55:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-14-2020 12:55:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-14-2020 12:55:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/14/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-14-2020 12:55:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP69J3	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.a Sample ID

Date	Location	User	Value	Reason
Aug-14-2020 12:55:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP69J3	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-14-2020 12:55:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP69J4	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-14-2020 12:55:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP69J4	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-14-2020 12:56:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP69J5	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-14-2020 12:56:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP69J5	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-14-2020 12:56:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPG680	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.d Sample ID

Date	Location	User	Value	Reason
Aug-14-2020 12:56:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPG680	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-14-2020 12:56:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPG681	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-14-2020 12:56:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPG681	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Aug-14-2020 12:56:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-14-2020 12:56:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-14-2020 12:57:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-14-2020 12:56:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-14-2020 12:56:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/14/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-14-2020 12:57:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP69HX	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.a Sample ID

Date	Location	User	Value	Reason
Aug-14-2020 12:57:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP69HX	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-14-2020 12:57:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-14-2020 12:57:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-14-2020 12:57:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-14-2020 12:57:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/14/2020 11:33	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-14-2020 12:57:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-14-2020 12:57:39	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	LEFT	
--	--	---------------------	------	--

7. Route:

Date	Location	User	Value	Reason
Aug-14-2020 12:57:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-14-2020 12:57:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 12:57:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-14-2020 12:57:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES - REACTOGENICITY E- DIARY COLLECTED FOR TH IS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Sep-04-2020 16:04:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/4/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:30

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[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-04-2020 16:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-04-2020 16:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FE VE R Were fever or systemic s N ymptoms present on the O last day the Subject Diar y was completed?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Sep-04-2020 16:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Sep-04-2020 16:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-04-2020 16:05:15 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)		(b) (4), (b) (6)	TI GU E Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	NO
--------------------	--	------------------	--	----

2.b Symptom:

Date	Location	User	Value	Reason
Sep-04-2020 16:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-04-2020 16:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-04-2020 16:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

2.c Symptom:

Date	Location	User	Value	Reason
Sep-04-2020 16:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-04-2020 16:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-04-2020 16:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: CH IL LS Were fever or systemic s N ymptoms present on the O last day the Subject Diar y was completed?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Sep-04-2020 16:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-04-2020 16:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.e

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-04-2020 16:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MIT ING Were fever or systemic symptoms present on t he last day the Subject Diary was completed?: NO	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Sep-04-2020 16:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-04-2020 16:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-04-2020 16:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic symptoms present on th e last day the Subject D iary was completed?: NO	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

2.f Symptom:

Date	Location	User	Value	Reason
Sep-04-2020 16:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Sep-04-2020 16:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-04-2020 16:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: NEW O R WORS ENED M USCLE P AIN Were fever or syste NO mic symptoms pre sent on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

2.g Symptom:

Date	Location	User	Value	Reason
Sep-04-2020 16:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERED MUS CLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-04-2020 16:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Sep-04-2020 16:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW O R WOR SENERED JOINT P AIN Were fever or syste NO mic symptoms pres ent on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

2.h Symptom:

Date	Location	User	Value	Reason
Sep-04-2020 16:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENER JOIN T PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-04-2020 16:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-04-2020 16:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-04-2020 16:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-04-2020 16:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: RE : DN ES S Were injection site react NO ions present on the last day the Subject Diary w as completed?:	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-04-2020 16:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-04-2020 16:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-04-2020 16:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction: SW : ELL ING Were injection site reac NO tions present on the las t day the Subject Diary was completed?:	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-04-2020 16:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-04-2020 16:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.c

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-04-2020 16:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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-04-2020 16:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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-04-2020 16:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

I. Date:

Date	Location	User	Value	Reason
Sep-04-2020 16:06:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/4/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-04-2020 16:06:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: 1 Temperature: 95.2 Temperature Unit: F Temperature Location: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-04-2020 16:06:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-08-2020 09:55:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed as per site response.
Sep-08-2020 08:34:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	not clinically significant
Sep-07-2020 03:58:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM1: Thanks for the response. Kindly confirm if

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

				the value is not clinically significant.
Sep-04-2020 16:08:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Sep-04-2020 16:06:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Temperature 95.2 F is outside of Normal Range 97 - 99.5 F.
Sep-04-2020 16:06:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 95.2	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-04-2020 16:06:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-04-2020 16:06:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Sep-04-2020 16:06:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-04-2020 16:06:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-04-2020 16:06:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/4/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-04-2020 16:06:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-04-2020 16:06:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Sep-04-2020 16:06:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::	Initial Entry
---	-----------------	-------------------------	--	---------------

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-04-2020 16:06:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-04-2020 16:06:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-04-2020 16:06:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-04-2020 16:06:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-04-2020 16:06:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-04-2020 16:07:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-04-2020 16:06:58 (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-04-2020 16:06:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/4/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-04-2020 16:07:03 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BHTYD9	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)	(b) (4), (b) (6)
--------------------	------------------

5.a Sample ID

Date	Location	User	Value	Reason
Sep-04-2020 16:07:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BHTYD9	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-04-2020 16:07:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-04-2020 16:07:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-04-2020 16:07:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-04-2020 16:07:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/4/2020 16:07	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-04-2020 16:07:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-04-2020 16:07:45	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	LEFT	
--	--	---------------------	------	--

7. Route:

Date	Location	User	Value	Reason
Sep-04-2020 16:07:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-04-2020 16:07:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-04-2020 16:07:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Oct-07-2020 10:23:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: Oct/7/2020	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[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
Oct-07-2020 10:23:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-07-2020 10:23:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: Symptom:: FE VE R Were fever or systemic s N ymptoms present on the O last day the Subject Dia ry was completed?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 10:23:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 10:23:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Oct-07-2020 10:23:33 (UTC-06:00) Central	ACV0PFEINFP6000	William Fernandez	Data Entry: Symptom:: FA	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)		(b) (4)	TI GU E Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	NO
--------------------	--	---------	--	----

2.b Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 10:23:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 10:23:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Oct-07-2020 10:23:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

2.c Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 10:23:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	<u>Data Entry:</u> HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 10:23:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	<u>Data Entry:</u> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Oct-07-2020 10:23:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	<u>Data Entry:</u> <u>Symptom::</u> CH IL LS Were fever or systemic s N ymptoms present on the O last day the Subject Dia ry was completed?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 10:23:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	<u>Data Entry:</u> CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 10:23:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	<u>Data Entry:</u> NO	Initial Entry

2.e

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Oct-07-2020 10:23:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: Symptom:: VO MIT ING Were fever or systemic symptoms present on t he last day the Subject Diary was completed?: NO	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 10:23:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 10:23:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Oct-07-2020 10:23:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic symptoms present on t he last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

2.f Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 10:23:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 10:23:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Oct-07-2020 10:23:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: Symptom:: NEW O R WORS ENED M USCLE PAIN Were fever or syst NO emic symptoms pr esent on the last d ay the Subject Dia ry was completed? :	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

2.g Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 10:23:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: NEW OR WORSENERED MUS CLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 10:23:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Oct-07-2020 10:23:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: Symptom:: NEW O R WOR SENERED JOINT P AIN Were fever or syste NO mic symptoms pres ent on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

2.h Symptom:

Date	Location	User	Value	Reason
Oct-07-2020 10:23:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: NEW OR WORSENER JOIN T PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 10:23:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Oct-07-2020 10:23:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Oct-07-2020 10:23:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-07-2020 10:23:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: Injection Site Reaction: RE : DN ES S Were injection site reac NO tions present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-07-2020 10:23:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	<u>Data Entry:</u> REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 10:23:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	<u>Data Entry:</u> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-07-2020 10:23:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	<u>Data Entry:</u> Injection Site Reaction SW :: ELL ING Were injection site rea NO ctions present on the la st day the Subject Diar y was completed?:	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-07-2020 10:23:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	<u>Data Entry:</u> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 10:23:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	<u>Data Entry:</u> NO	Initial Entry

5.c

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Oct-07-2020 10:23:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: 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
Oct-07-2020 10:23:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 10:23:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: NO	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (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:** 1018**Site Name:** (1018) Texas Center For Drug Development, Inc.**Subject No:** 10181159**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-07-2020 10:23:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-07-2020 10:23:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-07-2020 10:23:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-07-2020 10:23:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-07-2020 10:23:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: YES Date of Collection: Oct/7/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-07-2020 10:23:52 (UTC-06:00) Central	ACV0PFEINFP6000	William Fernandez	Data Entry: Sample ID: BP9FVK	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)		(b) (4)		
--------------------	--	---------	--	--

5.a Sample ID

Date	Location	User	Value	Reason
Oct-07-2020 10:23:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: BP9FVK	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-07-2020 10:23:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: Sample ID: BP9FVL	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-07-2020 10:23:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: BP9FVL	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-07-2020 10:24:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: Sample ID: BLB1PG	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-07-2020 10:24:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: BLB1PG	Initial Entry

5.d

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Oct-07-2020 10:24:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: Sample ID: BLB1PH	Initial Entry
---	-----------------	---------------------------------	--	---------------

5.d Sample ID

Date	Location	User	Value	Reason
Oct-07-2020 10:24:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: BLB1PH	Initial Entry

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Mar-02-2021 23:11:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: Mar/1/2021	Initial Entry

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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Mar-02-2021 23:11:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-02-2021 23:11:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-02-2021 23:12:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-02-2021 23:11:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-02-2021 23:11:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: YES Date of Collection: Mar/1/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-02-2021 23:12:55 (UTC-06:00) Central	ACV0PFEINFP6000	William Fernandez	Data Entry: Sample ID: BR1387	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)		(b) (4)		
--------------------	--	---------	--	--

5.a Sample ID

Date	Location	User	Value	Reason
Mar-02-2021 23:12:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: BR1387	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-02-2021 23:13:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: Sample ID: BR1388	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-02-2021 23:13:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: BR1388	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-02-2021 23:13:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: Sample ID: BS7GRN	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-02-2021 23:13:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: BS7GRN	Initial Entry

5.d

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Mar-02-2021 23:13:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: Sample ID: BS7GRP	Initial Entry
---	-----------------	---------------------------------	--	---------------

5.d Sample ID

Date	Location	User	Value	Reason
Mar-02-2021 23:13:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: BS7GRP	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-07-2020 10:26:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: Oct/7/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-07-2020 10:26:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-07-2020 10:26:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	William Fernandez (b) (4)	Data Entry: COMPLETED	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-12-2020 11:13:02 (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: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Nov-12-2020 11:13:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-12-2020 11:13:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-06-2020 12:40:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	Event of disc protrusion occurred after V3
Dec-03-2020 12:13:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	Waiting on PI review.
Nov-24-2020 13:41:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Opened	Clinical SAE report for Paresthesia reports event 'Small Lt central disc protrusion T5-T6 with minimal thecal sac indentation'. If subject's MRI occurred by V3

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

				(reporting window), please review for safety relevance & update AE CRF as appropriate
Nov-24-2020 13:39:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	reworded
Nov-24-2020 13:06:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Query Closed; this reported adverse event occurred after V3; not in reporting period
Nov-24-2020 07:43:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	Clinical On review of SAE report for Paresthesia, an event 'Small Lt central disc protrusion T5-T6 with minimal thecal sac indentation' was report, yet is not on AE CRF. Please review for clinical relevance and update AE CRF if appropriate
Nov-23-2020 07:57:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued: Opened	CLINICAL - Currently no new entry has been entered for an AE pertaining to "large mobile inguinal lymph nodes palpable"

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Nov-19-2020 17:31:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 3: An swere d	Will have PI update AE log in source and will update accordingly.
Nov-19-2020 15:14:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 3: Op ened	CLINICAL On review of the SAE report for Rt. Leg Paresthesia, an event of "large mobile inguinal lymph nodes palpable bilaterally" has been mentioned, yet it does not appear in the CRF. Please review for safety and update AE log CRF accordingly.
Nov-17-2020 21:26:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4) [REDACTED]	Query 1: Clo sed	Discrepancy has been closed.
Nov-17-2020 19:59:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: An swere d	Changed Information
Nov-17-2020 19:59:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry : Right Leg P aresth esia	Changed Information

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Nov-17-2020 06:55:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Rei ssued: Open ed	As per previous query, please split the term into LOWER BACK PAIN and BILATERAL LOWER EXTREMITY PAIN and RADICULAR PARESTHESIA and report as separate entries so they can be coded and analyzed.
Nov-16-2020 18:59:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Rei ssued: Candi date	Waiting for patient records
Nov-16-2020 17:40:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: An swere d	waiting for patient records
Nov-14-2020 14:23:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Clo sed	Appreciate the prompt response. Thank you.
Nov-14-2020 09:52:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Rei ssued: Open ed	Please leave query open until term is clarified with patient's records.

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Nov-13-2020 13:06:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: An swere d	Will update when medical records are received and reviewed.
Nov-13-2020 13:05:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 2: An swere d	Waiting on medical records. Updated SAE form was sent.
Nov-13-2020 12:37:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4) [REDACTED]	Query 2: Op ened	CLINICAL_ Multiple terms recorded. Kindly provide a final/underlying diagnosis based on MRI results or clinical assessment if available. Thank you.
Nov-12-2020 15:40:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4) [REDACTED]	Query 1: Op ened	Multiple concepts in the term LOWER BACK PAIN AND BILATERAL LOWER EXTREMITY PAIN WITH RADICULAR PARESTHESIA. Split the term into LOWER BACK PAIN and BILATERAL LOWER EXTREMITY PAIN and RADICULAR

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

				PARESTHESIA and report as separate entries. Thank you.
Nov-12-2020 11:13:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Lower back pain and bilateral lower extremity pain with radicular paresthesia	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-16-2020 14:34:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (b) (4)	Query 1: Closed	Response satisfies query
Nov-16-2020 14:29:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	PI feels possible due to no other obvious potential etiologies.
Nov-14-2020 06:14:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (b) (4)	Query 1: Reissued:Opened	Please can you confirm why the PI felt this was related to IP? It has began 46 days post dose 2. thanks
Nov-13-2020 13:04:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Start date is correct.
Nov-13-2020 05:48:45	ACV0PFEINFP6000	Ahmed	Query 1: Opened	Clin: Lower back

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-06:00) Central Time (US & Canada)		Hassan (b) (4)		pain and bilateral lower extremity pain with radicular paresthesia: Please can you review the start date of this AE, as currently it is listed as related to IP but began 46 days PD2. Thanks
Nov-12-2020 11:13:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/20/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-05-2021 06:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 1: Closed	Response satisfies query
Mar-03-2021 16:01:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Still ongoing.
Mar-03-2021 13:45:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 1: Opened	Clin: Please confirm if this AE is still ongoing
Nov-12-2020 11:13:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-12-2020 11:13:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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-21-2020 14:43:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	Query closed; will follow for SAE update with the requested COVID test info
Nov-19-2020 17:25:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	Test was performed on 23Oct2020 and was reported negative. We will update the SAE form.
Nov-19-2020 15:18:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Opened	Clinical COVID test status (yes/no) during Hosp was not submitted to the SAE, as state 13Nov20. Please submit the follow-up SAE form to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results.
Nov-13-2020 18:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Query closed; will follow for SAE update with the requested IP injection dates
Nov-13-2020 18:07:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Query closed; will follow for SAE update with the requested COVID test info

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1018**Subject No:** 10181159**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Verified**Site Name:** (1018) Texas Center For Drug Development, Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44

Nov-13-2020 13:06:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 3: Answered	SAE form was corrected.
Nov-13-2020 13:03:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 4: Answered	SAE form updated
Nov-13-2020 08:01:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 4: Opened	Clinical COVID test status (yes/no) during Hosp was not reported in the SAE. Please submit a follow-up SAE form [#10181159] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results.
Nov-13-2020 08:00:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 3: Opened	CLINICAL - Per CRF, Inj #1 given on 8/14 and Inj #2 on 9/4; however, in SAE Inj #1 given on 8/12 and Inj #2 on 9/1. Please review, harmonize reporting and update in appropriate location.
Nov-13-2020 04:07:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-12-2020 11:13:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Nov-12-2020 11:13:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: YES Is this serious event associate	New Information

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

			<p>d 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>NO</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>YES</p>	
Nov-12-2020 11:13:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Is this adverse event serious?' is reported 'Yes', but at least one seriousness criteria is missing. Please review and update as appropriate.
Nov-12-2020 11:13:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Lower back pain and bilateral lower extremity pain with radicular paresthesia: Response to "Is the

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

				adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-12-2020 11:13:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Other medically important serious event YES	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

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-12-2020 11:13:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-12-2020 11:13:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-12-2020 11:13:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-12-2020 11:13:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-12-2020 11:13:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (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, Verified

Site No: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Nov-12-2020 11:13:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry
---	-----------------	---------------------	--	---------------

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

Date	Location	User	Value	Reason
Nov-12-2020 11:13:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Nov-13-2020 04:07:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020447492	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Jan-06-2021 13:47:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/16/2020	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

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

Date	Location	User	Value	Reason
Jan-22-2021 12:02:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed t o have received only placebo at Vaccination 1/2	Transcription Error
Jan-06-2021 13:47:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is NOT willing to ret urn for Vaccination 3 OR otherwi se not eligible	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-06-2021 13:46:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/16/2020	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-06-2021 13:46:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1018

Subject No: 10181159

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Oct-07-2020 10:26:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-14-2020 12:55:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-14-2020 12:41:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-07-2020 10:26:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/7/2020	Initial Entry
Aug-14-2020 12:55:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/14/2020	Initial Entry
Aug-14-2020 12:41:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/14/2020	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (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: 1018

Site Name: (1018) Texas Center For Drug Development, Inc.

Subject No: 10181159

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

I. Casebook Signature

Date	Location	User	Value	Reason
Oct-12-2020 14:16:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae401b\Final\Final On: 01-Apr-2021 05:30 (GMT)