

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: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[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	30 JUN 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: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Informed Consent

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

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11611016]
2.	Birth Date:	(b) (6) /2000
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclusion criteria (NO).

Inclusion Criteria

1.a	Inclusion Number:	1
	Criterion Description:	Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN01A00
1.b	Inclusion Number:	2
	Criterion Description:	Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN02A00
1.c	Inclusion Number:	3
	Criterion Description:	Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN03A00
1.d	Inclusion Number:	4
	Criterion Description:	Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN04A00

Exclusion Criteria

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Header Text: c4591001

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Form Version: 30-Jul-2020 21:27

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

2.a	Exclusion Number:	1
	Criterion Description:	Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX01A00
2.b	Exclusion Number:	2
	Criterion Description:	Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX02A00
2.c	Exclusion Number:	3
	Criterion Description:	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX03A00
2.d	Exclusion Number:	4
	Criterion Description:	Receipt of medications intended to prevent COVID-19
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX04A00
2.e	Exclusion Number:	8
	Criterion Description:	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX08A00

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

2 f	Exclusion Number:	10
	Criterion Description:	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX10A00
2.g	Exclusion Number:	11
	Criterion Description:	Women who are pregnant or breastfeeding
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX11A00
2 h	Exclusion Number:	12
	Criterion Description:	Previous vaccination with any coronavirus vaccine
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX12A00
2.i	Exclusion Number:	13
	Criterion Description:	Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX13A01
2.j	Exclusion Number:	15
	Criterion Description:	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX14A01

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

2 k	Exclusion Number:	16
	Criterion Description:	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX15A01
2.1	Exclusion Number:	17
	Criterion Description:	Previous participation in other studies involving study intervention containing lipid nanoparticles
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX16A01
2.m	Exclusion Number:	22
	Criterion Description:	Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX21A01

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Aug/1/2020
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: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[seasonal allergies]
	Start Date:	UNK/UNK/2013
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[iron deficiency]
	Start Date:	UNK/UNK/2013
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[heartburn]
	Start Date:	Feb/UNK/2020
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[mild depression]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[lumbar pain]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES
1.f	Line/MH Number:	[]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[]
	Start Date:	//
	Ongoing:	

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/1/2020
2.	Weight:	[74.8]
3.	Unit:	kg
4.	Height:	[160.0]
5.	Unit:	cm
6.	Body Mass Index:	[29.2]

Vital Signs Details

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

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Lab Urinalysis

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

Lab Result

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

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Aug/1/2020
2.	Randomization Number:	[41384]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/1/2020
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	[BP3D3G]
5.b	Sample ID	[BP3D3H]
5.c	Sample ID	[BP3D3J]
5.d	Sample ID	[BP3D3K]
5.e	Sample ID	[BP3D3L]
5.f	Sample ID	[BPLL5G]
5.g	Sample ID	[BPLL5H]
5.h	Sample ID	[BPLL5J]
5.i	Sample ID	[BPLL5K]

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/1/2020
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	[BP3D8D]
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090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[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/1/2020 16:15
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

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/19/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:30

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Status: Data Complete, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[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

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (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, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Nov/19/2020
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Vital Signs Details

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Nov/19/2020
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:	

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Nov/19/2020
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	[BP3DBV]
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090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[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:	Nov/19/2020 10:37
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

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Dec/17/2020
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, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[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

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (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, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/17/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP3DCZ]
5.b	Sample ID	[BPLLC9]
5.c	Sample ID	[BPLLCB]

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET
on Dec/02/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Date of Visit

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

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Dec/02/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Dec/2/2020
2.	Date of First Symptom Started:	Nov/29/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Dec/7/2020

Symptoms

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

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Dec/02/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

4.i	Symptoms:	VOMITING
	Was symptom present?	NO

Symptoms - Other

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

5.b	Symptoms - Other Text:	[Nasal congestion]
-----	------------------------	--------------------

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Dec/2/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN
on Dec/02/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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[Form Audit Trail](#)

Microbiology Specimen

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

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Dec/02/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[RW79132]
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090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB on Dec/02/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[subject will collect self swab]

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION
on Dec/02/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1161**Site Name:** (1161) Benchmark Research - San Angelo**Subject No:** 11611016**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23[eCRF Audit Trail History](#)**Health Care Utilization**

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

Health Care Utilization Other

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

Health Care Utilization

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT
on Dec/02/2020

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Respiratory Treatment

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS
on Dec/02/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.					Repeating Pages

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE
on Dec/02/2020

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Illness Details

1.	Category of Clinical Event:	
2.	Subcategory of Clinical Event:	
3.	Was a diagnosis obtained?	
4.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 30-Jul-2020 21:27

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	Repeating Pages

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Dec/02/2020

Form Version: 30-Jul-2020 21:27

Form Status: Not Started

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Lab Chemistry Details

1.	Lab Panel:	
2.	Laboratory Name and Address	[]
3.	Collection Date:	//
4.	Specimen Type:	

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 30-Jul-2020 21:28

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

#	Category for Lab Test	Vendor Name (DE RIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Dec/02/2020

Form Version: 30-Jul-2020 21:28

Form Status: Not Started

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Laboratory Data Hematology

1.	Lab Panel:	
2.	Laboratory Name and Address	[]
3.	Collection Date:	//
4.	Specimen Type:	

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 30-Jul-2020 21:27

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

#	Date:	Vital Signs Details			Form Instance
1.		Record Identifier:	Systolic:	Diastolic:	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Dec/02/2020

Form Version: 30-Jul-2020 21:27

Form Status: Not Started

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	Systolic:	[]
	Diastolic:	[]
	Respiratory Rate in respirations/minute:	[]
	Heart Rate in beats/minute:	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 30-Jul-2020 21:28

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

#	Date:	Vital Signs Details		Form Instance
1.		Record Identifier:	Oxygen Saturation	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Dec/02/2020

Form Version: 30-Jul-2020 21:28

Form Status: Not Started

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.				Repeating Pages

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS
on Dec/02/2020

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Oxygenation Parameters

1.	Date Time of Assessment:	//
2.	Arterial Blood Gases PaO2 (mmHg):	[]
3.	FiO2 (Fraction of Inhaled Oxygen):	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
on Dec/02/2020

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Concomitant Medications

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

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING
on Dec/02/2020

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Imaging

1.	Date of Assessment:	//
2.	Location of Assessment:	
3.	Type of Imaging Exam:	
4.	Assessment:	

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled **Form:** DATE OF VISIT - ILLNESS CONVALESCENT
Visit on Dec/30/2020

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Date of Visit

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

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A1
----	-------------------------	----------

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Visit on Dec/30/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/30/2020
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	[BP3DD7]
5.b	Sample ID	[BPLLCV]
5.c	Sample ID	[BPLLCW]

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Feb/25/2021

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Form Comments](#)

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/25/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/25/2021

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

Unplanned Assessments

	Assessments	Not Applicable	Comments
1.			

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/25/2021

Form: CONTACT OUTCOME - UNPLANNED

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

Contact Outcome

1.	Contact Type:	Not Applicable	Comments
2.	Was contact made?	Not Applicable	Comments
3.	Comments:	Not Applicable []	Comments

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/25/2021

Form: VITAL SIGNS - TEMP

Form Version: 20-Feb-2021 02:16

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

Vital Signs

1.	Date:	Not Applicable _____ //	Comments
----	-------	-------------------------------	--------------------------

Vital Signs Details

2.a	Record Identifier:	Not Applicable _____ 1	
	Temperature:	Not Applicable _____ []	Comments
	Unit:	Not Applicable _____ 	Comments
	Temperature Location:	Not Applicable _____ 	Comments

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Dec/17/2020
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: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (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: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Exposure during Pregnancy	Jan/17/2021 UNK:UNK	YES	Repeating Pages

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Exposure during Pregnancy]
4.	Start Date Time:	Jan/17/2021 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [relations]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

#	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: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[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	[]

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

#	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: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[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:	//

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[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?	

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

#	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: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

#	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: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[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: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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:	

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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?	

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (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: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Informed Consent - Asymptomatic Surveillance

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

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

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: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (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: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per other protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2
----	---	--

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Feb/22/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Status: Not Started

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Informed Consent - Further Vaccination

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

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Not Started

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Inclusion Criteria Not Met

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

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	
----	--	--

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Status: Not Started

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Disposition - Screening for Further Vaccination

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Dec/17/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Darrell Herrington	Approved	Mar-08-2021 12:03:13 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, DarrellHerrington, 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.

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/25/2021

Form: DATE OF VISIT - Comments

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-05-2021 16:25:53 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	not applicable

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/25/2021

Form: UNPLANNED VISIT - Comments

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-01-2021 15:37:12 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Unplanned 1

Form Version: 22-Apr-2020 21:04

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: UNPLANNED VISIT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
1	Mar-01-2021 15:37:12 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/25/2021

Form: CONTACT OUTCOME - UNPLANNED - Comments

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
Form	Mar-01-2021 15:36:28 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Unplanned 1

Form Version: 22-Apr-2020 21:04

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: CONTACT OUTCOME - UNPLANNED - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
1	Mar-01-2021 15:36:28 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Unplanned 1

Form Version: 22-Apr-2020 21:04

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: CONTACT OUTCOME - UNPLANNED - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
2	Mar-01-2021 15:36:28 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Unplanned 1

Form Version: 22-Apr-2020 21:04

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: CONTACT OUTCOME - UNPLANNED - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
3	Mar-01-2021 15:36:28 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/25/2021

Form: VITAL SIGNS - TEMP - Comments

Form Version: 20-Feb-2021 02:16

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-01-2021 15:37:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
Form	Feb-25-2021 17:11:09 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
Form	Feb-25-2021 17:09:18 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: Unplanned 1

Form Version: 20-Feb-2021 02:16

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
1	Mar-01-2021 15:37:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
1	Feb-25-2021 17:11:09 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
1	Feb-25-2021 17:09:18 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: Unplanned 1

Form Version: 20-Feb-2021 02:16

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
2.a	Mar-01-2021 15:37:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
2.a	Feb-25-2021 17:11:09 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
2.a	Feb-25-2021 17:09:18 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: Unplanned 1

Form Version: 20-Feb-2021 02:16

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
2.a	Mar-01-2021 15:37:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
2.a	Feb-25-2021 17:11:09 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
2.a	Feb-25-2021 17:09:18 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: Unplanned 1

Form Version: 20-Feb-2021 02:16

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
2.a	Mar-01-2021 15:37:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
2.a	Feb-25-2021 17:11:09 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
2.a	Feb-25-2021 17:09:18 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Darrell Herrington	Approved	Mar-08-2021 12:03:13 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:

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

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

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

(b) (6)	N/A	Mar-03-2021 16:42:21 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Darrell Herrington	Approved	Mar-02-2021 14:05:58 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

(b) (6)	N/A	Feb-22-2021 13:57:59 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Darrell Herrington	Approved	Jan-05-2021 08:33:15 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, DarrellHerrington, 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	Dec-04-2020 12:07:24 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Darrell Herrington	Approved	Dec-02-2020 17:19:20 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, DarrellHerrington, 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	Dec-02-2020 15:41:07 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Darrell Herrington	Approved	Dec-01-2020 16:02:24 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Affidavit:

By my dated signature below, I, DarrellHerrington, 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-19-2020 16:24:02 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Darrell Herrington	Approved	Sep-11-2020 17:34:16 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, DarrellHerrington, 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.

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-02-2020 15:17:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 30 JUN 2020	Transcription Error
Aug-02-2020 15:08:05 (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-02-2020 15:08:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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I. Consent Was:

Date	Location	User	Value	Reason
Aug-02-2020 15:08:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Aug/1/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Subject ID

Date	Location	User	Value	Reason
Aug-02-2020 15:07:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11611016	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-02-2020 15:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) /2000	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-02-2020 15:09:00 (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-02-2020 15:09:00 (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-02-2020 15:09:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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I. Date of Visit

Date	Location	User	Value	Reason
Aug-02-2020 15:10:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/1/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1.a

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Inclusion Number: Criterion Description: Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage) Criterion met?: Criterion ID: IN01A00 Use only: (For Pfizer only):	Initial Entry

1.a Inclusion Number:

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

1.a Criterion Description:

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive,	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

			ve, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)	
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1.a Criterion met?

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.a Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN01A00	Initial Entry

1.b

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Inclusion Number: Criterion Definition: Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures Criterion met?: YES Criterion ID: (For Pfizer use only): IN02A00	Initial Entry

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Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1161**Site Name:** (1161) Benchmark Research - San Angelo**Subject No:** 11611016**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23***1.b Inclusion Number:***

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

1.b Criterion Description:

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures	Initial Entry

1.b Criterion met?

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.b Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN02A00	Initial Entry

1.c

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Inclus 3 ion Nu mber:	Initial Entry

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Subject No: 11611016

Generated By: (b) (4)

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Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

			<p>Criterion Description: Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study</p> <p>Criterion met?: YES</p> <p>Criterion ID: IN03A00 : (For Pfizer use only):</p>	
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Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

I.c Inclusion Number:

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

I.c Criterion Description:

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study	Initial Entry

I.c Criterion met?

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.c Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN03A00	Initial Entry

I.d

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Inclusion Number:	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

			<p>Criteria Description: Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol</p> <p>Criteria met?: YES</p> <p>Criteria ID: IN04A00 (For Pfizer use only)</p>	
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

1.d Inclusion Number:

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4	Initial Entry

1.d Criterion Description:

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol	Initial Entry

1.d Criterion met?

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.d Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN04A00	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number:	Initial Entry

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Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

			<p>Criterion Description: Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation</p> <p>Criterion met?: NO</p> <p>Criterion ID: EX01A00</p> <p>Use only: (For Pfizer use only):</p>	
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2.a Exclusion Number:

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Criterion Description:

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation	Initial Entry

2.a Criterion met?

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

2.a Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX01A00	Initial Entry

2.b

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: Criterion Description: Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV) Criterion met?: NO Criterion ID: (For Pfizer use only): EX02A00	Initial Entry

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Header Text: c4591001

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

2.b Exclusion Number:

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

2.b Criterion Description:

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)	Initial Entry

2.b Criterion met?

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX02A00	Initial Entry

2.c

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclus 3 ion Number:	Initial Entry

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Header Text: c4591001

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

			<p>Criteria History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)</p> <p>Criteria met?:</p> <p>Criteria ID: EX03A00 (For Pfizer use only):</p>	
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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

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2.c Exclusion Number:

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

2.c Criterion Description:

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)	Initial Entry

2.c Criterion met?

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX03A00	Initial Entry

2.d

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: 4 Criterion Description: Receipt of medications intended to prevent COVID-19	Initial Entry

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

			Criterion met?: Criterion ID EX04A00 : (For Pfizer use only):	
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2.d Exclusion Number:

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4	Initial Entry

2.d Criterion Description:

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Receipt of medications intended to prevent COVID-19	Initial Entry

2.d Criterion met?

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX04A00	Initial Entry

2.e

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number:	Initial Entry

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

			<p>Criteria: Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination</p> <p>Criteria met?: NO</p> <p>Criteria ID: EX08A00</p> <p>(For Pfizer use only):</p>	
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Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

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2.e Exclusion Number:

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 8	Initial Entry

2.e Criterion Description:

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination	Initial Entry

2.e Criterion met?

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX08A00	Initial Entry

2.f

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number:	Initial Entry

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Subject No: 11611016

Generated By: (b) (4)

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Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

			<p>Criteria Bleeding diathesis or condition associated with on Des ndition associated with criptio prolonged bleeding that n: would, in the opinion of the investigator, contraindicate intramuscular injection</p> <p>Criteria NO on met ?:</p> <p>Criteria EX10A00 on ID: (For P fizer u se only):</p>	
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Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

2.f Exclusion Number:

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 10	Initial Entry

2.f Criterion Description:

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bleeding diathesis or condition as associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection	Initial Entry

2.f Criterion met?

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX10A00	Initial Entry

2.g

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: 11 Criterion Description: Women who are pregnant or breastfeeding	Initial Entry

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Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

			Criterion met NO ?: Criterion ID: EX11A00 (For Pfizer use only):	
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2.g Exclusion Number:

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 11	Initial Entry

2.g Criterion Description:

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Women who are pregnant or breastfeeding	Initial Entry

2.g Criterion met?

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX11A00	Initial Entry

2.h

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: 12	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

			Criterion Description: Previous vaccination with any coronavirus vaccine Criterion met?: NO Criterion ID: EX12A00 (For Pfizer use only):	
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2.h Exclusion Number:

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 12	Initial Entry

2.h Criterion Description:

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Previous vaccination with any coronavirus vaccine	Initial Entry

2.h Criterion met?

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX12A00	Initial Entry

2.i

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

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

Exclusion Number: 13

Criterion Description: Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids

Criterion met?: NO

Criterion ID: (For Pfizer use only): EX13A01

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

2.i Exclusion Number:

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 13	Initial Entry

2.i Criterion Description:

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids	Initial Entry

2.i Criterion met?

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.i Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX13A01	Initial Entry

2.j

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclus 15 ion Number:	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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Site No: 1161

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Subject Initials: ---

Generated By: (b) (4)

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			<p>Criteria Description: Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study</p> <p>Criteria Met: NO</p> <p>Criteria ID: EX14A01 (For Pfizer use only)</p>	
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090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

2.j Exclusion Number:

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 15	Initial Entry

2.j Criterion Description:

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study	Initial Entry

2.j Criterion met?

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.j Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX14A01	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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2.k				
Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Exclusion Number: 16</p> <p>Criterion Description: Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation</p> <p>Criterion met?: NO</p> <p>Criterion ID: (For Pfizer use only): EX15A01</p>	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

2.k Exclusion Number:

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 16	Initial Entry

2.k Criterion Description:

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation	Initial Entry

2.k Criterion met?

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.k Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX15A01	Initial Entry

2.l

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusio 17 n Numb er:	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

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			Criterion Description: Previous participation in other studies involving study intervention containing lipid nanoparticles Criterion met?: NO Criterion ID: (For Pfizer use only): EX16A01	
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2.1 Exclusion Number:

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 17	Initial Entry

2.1 Criterion Description:

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Previous participation in other studies involving study intervention containing lipid nanoparticles	Initial Entry

2.1 Criterion met?

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.1 Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX16A01	Initial Entry

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Subject Initials: ---

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2.m

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Exclusion Number: 22</p> <p>Criterion Description: Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members</p> <p>Criterion ID: EX21A01</p> <p>Criterion ID: (For Pfizer use only):</p>	Initial Entry

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Header Text: c4591001

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

2.m Exclusion Number:

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 22	Initial Entry

2.m Criterion Description:

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff or herwise supervised by the investigator, and their respective family members	Initial Entry

2.m Criterion met?

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.m Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-02-2020 15:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX21A01	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-02-2020 15:14:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/1/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-02-2020 15:14:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-02-2020 15:14:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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I.a

Date	Location	User	Value	Reason
Aug-02-2020 15:21:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 1 : Medical History T seasonal aller erm: gies Start Date: UNK/UNK/2 013 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-02-2020 15:21:39 (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-02-2020 15:21:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: seasonal allergies	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Aug-02-2020 15:21:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2013	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Aug-02-2020 15:21:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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Header Text: c4591001

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Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

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I.b

Date	Location	User	Value	Reason
Aug-02-2020 15:22:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 2 : Medical History Term: iron deficiency Start Date: UNK/UNK/2013 Ongoing: YES	Initial Entry

I.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-02-2020 15:22:41 (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-02-2020 15:22:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: iron deficiency	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Aug-02-2020 15:22:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2013	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Aug-02-2020 15:22:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.c

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Subject No: 11611016

Generated By: (b) (4)

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Form Status: Data Complete, Frozen, Verified

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Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Date	Location	User	Value	Reason
Aug-02-2020 15:23:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Te heartburn rm: Start Date: Feb/UNK/20 20 Ongoing: YES	Initial Entry

I.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-02-2020 15:23:11 (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-02-2020 15:23:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: heartburn	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-02-2020 15:23:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/UNK/2020	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-02-2020 15:23:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Aug-02-2020 15:25:21	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

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Generated By: (b) (4)

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Form Status: Data Complete, Frozen, Verified

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Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

(UTC-06:00) Central Time (US & Canada)		(autocalc)	Line/MH Number 4 : Medical History Term: mild depression Start Date: UNK/UNK/2019 Ongoing: YES
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1.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-02-2020 15:25:21 (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
Aug-02-2020 15:25:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: mild depression	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Aug-02-2020 15:25:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2019	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Aug-02-2020 15:25:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.e

Date	Location	User	Value	Reason
Aug-02-2020 15:25:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 5 :	Initial Entry

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Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Subject Initials: ---

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			Medical History Term: Start Date: UNK/UNK/2016 Ongoing: YES
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I.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-02-2020 15:25:54 (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-02-2020 15:25:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: lumbar pain	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Aug-02-2020 15:25:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2016	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Aug-02-2020 15:25:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

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Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date:

Date	Location	User	Value	Reason
Aug-02-2020 15:31:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/1/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-02-2020 15:31:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 74.8	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-02-2020 15:31:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-02-2020 15:31:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 160.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-02-2020 15:31:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-02-2020 15:31:20 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 29.2	Initial Entry

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Subject No: 11611016

Generated By: (b) (4)

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Time (US & Canada)				
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7.a

Date	Location	User	Value	Reason
Aug-02-2020 15:31:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 98.6 Temperature Unit: F Temperature Location:: FOREHEAD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-02-2020 15:31:20 (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-02-2020 15:31:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.6	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-02-2020 15:31:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-02-2020 15:31:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (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: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Lab Panel:

Date	Location	User	Value	Reason
Aug-02-2020 15:32:55 (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-02-2020 15:32:55 (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-02-2020 15:32:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/1/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-02-2020 15:32:55 (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
Aug-02-2020 15:32:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (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: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Aug-02-2020 15:32:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::	Initial Entry
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-02-2020 15:32:55 (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-02-2020 15:32:55 (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
Aug-02-2020 15:32:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Randomization Date :

Date	Location	User	Value	Reason
Aug-02-2020 15:33:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/1/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-02-2020 15:33:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 41384	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (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: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Data Origin

Date	Location	User	Value	Reason
Aug-02-2020 15:33:27 (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-02-2020 15:33:27 (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-10-2020 15:14:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-04-2020 05:07:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-02-2020 15:33:27 (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-02-2020 15:33:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection:	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (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: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

			Aug/1/2020	
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5.a

Date	Location	User	Value	Reason
Aug-10-2020 15:14:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP3D3G	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-10-2020 15:14:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP3D3G	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-10-2020 15:14:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP3D3H	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-10-2020 15:14:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP3D3H	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-10-2020 15:28:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP3D3J	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (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: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.c Sample ID

Date	Location	User	Value	Reason
Aug-10-2020 15:28:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP3D3J	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-10-2020 15:28:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP3D3K	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-10-2020 15:28:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP3D3K	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-10-2020 15:29:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP3D3L	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-10-2020 15:29:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP3D3L	Initial Entry

5.f

Date	Location	User	Value	Reason
Aug-10-2020 15:31:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPLL5G	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (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: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.f Sample ID

Date	Location	User	Value	Reason
Aug-10-2020 15:31:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPLL5G	Initial Entry

5.g

Date	Location	User	Value	Reason
Aug-10-2020 15:31:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPLL5H	Initial Entry

5.g Sample ID

Date	Location	User	Value	Reason
Aug-10-2020 15:31:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPLL5H	Initial Entry

5.h

Date	Location	User	Value	Reason
Aug-10-2020 15:31:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPLL5J	Initial Entry

5.h Sample ID

Date	Location	User	Value	Reason
Aug-10-2020 15:31:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPLL5J	Initial Entry

5.i

Date	Location	User	Value	Reason
Aug-10-2020 15:31:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPLL5K	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (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: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.i Sample ID

Date	Location	User	Value	Reason
Aug-10-2020 15:31:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPLL5K	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Data Origin

Date	Location	User	Value	Reason
Aug-02-2020 15:33:36 (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-02-2020 15:33:36 (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-10-2020 15:32:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-04-2020 05:07:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-02-2020 15:33:36 (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-02-2020 15:33:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection:	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (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: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

			Aug/1/2020	
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5.a

Date	Location	User	Value	Reason
Aug-10-2020 15:32:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP3D8D	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-10-2020 15:32:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP3D8D	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-02-2020 15:34:03 (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-02-2020 15:34:03 (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-02-2020 15:34:03 (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-02-2020 15:34:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/1/2020 16:15	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-02-2020 15:34:03 (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-02-2020 15:34:03 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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

Date	Location	User	Value	Reason
Aug-02-2020 15:34:03 (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-02-2020 15:34:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-02-2020 15:34:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-11-2020 05:24:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-10-2020 15:13:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Aug-10-2020 15:13:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES - REACTOGENICITY E-DIARY COLLECTED F OR THIS SUBJECT	Transcription Error
Aug-07-2020 04:46:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM Query: Patient is expected to be included in the Reactogenicity subset. Please review and update as appropriate
Aug-02-2020 15:34:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECT ED FOR THIS SUBJECT	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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I. Date of Visit

Date	Location	User	Value	Reason
Nov-22-2020 23:30:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed per SITE response, added to PD tracker for Clinical review
Nov-20-2020 17:36:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	visit 2 is oow due to study on pause per sponsor
Nov-20-2020 01:54:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	PDQ: DOV at this visit is out of window (87 day) from DOV (01/Aug /2020) at VID1VX1L. Please either update DOV or confirm whether visit is out of window due to temporary delay of vaccination/ else provide details as appropriate.
Nov-19-2020 16:24:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/19/2020	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:30

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Nov-19-2020 16:24:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-19-2020 16:24:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FE VE R Were fever or systemic symptoms present on the last day the Subject Diary was completed?: N O	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Nov-19-2020 16:24:57 (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
Nov-19-2020 16:24:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Nov-19-2020 16:24:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (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, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

			GU E NO	
Were fever or systemic symptoms present on the last day the Subject Diary was completed?:				

2.b Symptom:

Date	Location	User	Value	Reason
Nov-19-2020 16:24:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Nov-19-2020 16:24:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Nov-19-2020 16:24:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (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, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

2.c Symptom:

Date	Location	User	Value	Reason
Nov-19-2020 16:24:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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
Nov-19-2020 16:24:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Nov-19-2020 16:24:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: CH IL LS Were fever or systemic sy NO mptoms present on the las t day the Subject Diary wa s completed?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Nov-19-2020 16:24:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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
Nov-19-2020 16:24:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (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, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Date	Location	User	Value	Reason
Nov-19-2020 16:24:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MIT ING Were fever or systemic sy NO mptoms present on the la st day the Subject Diary was completed?:	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Nov-19-2020 16:24:57 (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
Nov-19-2020 16:24:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Nov-19-2020 16:24:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic sy NO mptoms present on the la st day the Subject Diary was completed?:	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (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, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

2.f Symptom:

Date	Location	User	Value	Reason
Nov-19-2020 16:24:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	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
Nov-19-2020 16:24:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Nov-19-2020 16:24:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED MUSCLE PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Nov-19-2020 16:24:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSE NED MUSCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Nov-19-2020 16:24:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (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, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

2.h

Date	Location	User	Value	Reason
Nov-19-2020 16:24:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED JOI NT PAIN Were fever or syste NO mic symptoms prese nt on the last day the Subject Diary was co mpleted?:	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Nov-19-2020 16:24:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSE NED JOINT P AIN	Initial Entry

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

Date	Location	User	Value	Reason
Nov-19-2020 16:24:57 (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
Nov-19-2020 16:24:57 (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
Nov-19-2020 16:24:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (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, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.a

Date	Location	User	Value	Reason
Nov-19-2020 16:24:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactio NO ns present on the last day the Subject Diary was co mpleted?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-19-2020 16:24:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Nov-19-2020 16:24:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-19-2020 16:24:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SW ELL ING Were injection site reacti NO ons present on the last da y the Subject Diary was c ompleted?:	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (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, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-19-2020 16:24:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Nov-19-2020 16:24:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-19-2020 16:24:57 (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
Nov-19-2020 16:24:57 (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
Nov-19-2020 16:24:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date:

Date	Location	User	Value	Reason
Nov-19-2020 16:27:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/19/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-19-2020 16:27:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 98.3 Temperature Unit: F Temperature Locat FOREHE ion:: AD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-19-2020 16:27:10 (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
Nov-19-2020 16:27:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.3	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Nov-19-2020 16:27:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

2.a Temperature Location:

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Date	Location	User	Value	Reason
Nov-19-2020 16:27:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Lab Panel:

Date	Location	User	Value	Reason
Nov-19-2020 16:27:56 (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
Nov-19-2020 16:27:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Nov-19-2020 16:27:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/19/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Nov-19-2020 16:27:56 (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
Nov-19-2020 16:27:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (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, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Nov-19-2020 16:27:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::	Initial Entry
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-19-2020 16:27:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Nov-19-2020 16:27:56 (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
Nov-19-2020 16:27:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (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, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Data Origin

Date	Location	User	Value	Reason
Nov-19-2020 16:28:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-19-2020 16:28:30 (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
Nov-23-2020 11:03:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-20-2020 04:10:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-19-2020 16:28:30 (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.
Nov-19-2020 16:28:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/19/2020	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (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, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.a

Date	Location	User	Value	Reason
Nov-23-2020 11:03:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP3DBV	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-23-2020 11:03:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP3DBV	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Nov-19-2020 16:29:40 (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
Nov-19-2020 16:29:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Nov-19-2020 16:29:40 (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
Nov-19-2020 16:29:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/19/2020 10:37	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Nov-19-2020 16:29:40 (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
Nov-19-2020 16:29:40 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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

Date	Location	User	Value	Reason
Nov-19-2020 16:29:40 (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
Nov-19-2020 16:29:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Nov-19-2020 16:29:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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I. Date of Visit

Date	Location	User	Value	Reason
Dec-17-2020 12:49:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/17/2020	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (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, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Dec-17-2020 12:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Dec-17-2020 12:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FE VE R Were fever or systemic sy N mptoms present on the last O day the Subject Diary was completed?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Dec-17-2020 12:49:43 (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
Dec-17-2020 12:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Dec-17-2020 12:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (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, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

			GU E	
			Were fever or systemic sy mptoms present on the las t day the Subject Diary wa s completed?:	NO

2.b Symptom:

Date	Location	User	Value	Reason
Dec-17-2020 12:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Dec-17-2020 12:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Dec-17-2020 12:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: HE AD AC HE Were fever or systemic sy mptoms present on the la st day the Subject Diary was completed?:	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (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, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

2.c Symptom:

Date	Location	User	Value	Reason
Dec-17-2020 12:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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
Dec-17-2020 12:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Dec-17-2020 12:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: CH IL LS Were fever or systemic sy NO mptoms present on the last day the Subject Diary was completed?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Dec-17-2020 12:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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
Dec-17-2020 12:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (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, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Date	Location	User	Value	Reason
Dec-17-2020 12:49:43 (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 the last day the Subject Diary was completed?: NO	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Dec-17-2020 12:49:43 (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
Dec-17-2020 12:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Dec-17-2020 12:49:43 (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 the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (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, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

2.f Symptom:

Date	Location	User	Value	Reason
Dec-17-2020 12:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	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
Dec-17-2020 12:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Dec-17-2020 12:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED MU SCLE PA IN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Dec-17-2020 12:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD MUSCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Dec-17-2020 12:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (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, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

2.h

Date	Location	User	Value	Reason
Dec-17-2020 12:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED JOINT PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Dec-17-2020 12:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSE NED JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Dec-17-2020 12:49:43 (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
Dec-17-2020 12:49:43 (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
Dec-17-2020 12:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (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, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.a

Date	Location	User	Value	Reason
Dec-17-2020 12:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Dec-17-2020 12:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Dec-17-2020 12:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-17-2020 12:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SW ELL ING Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (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, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Dec-17-2020 12:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Dec-17-2020 12:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-17-2020 12:49:43 (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
Dec-17-2020 12:49:43 (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
Dec-17-2020 12:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (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, Frozen, Verified**Site No:** 1161**Site Name:** (1161) Benchmark Research - San Angelo**Subject No:** 11611016**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Dec-17-2020 12:50:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-17-2020 12:50:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-17-2020 15:53:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-17-2020 12:50:02 (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.
Dec-17-2020 12:50:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/17/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-17-2020 15:53:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP3DCZ	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, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.a Sample ID

Date	Location	User	Value	Reason
Dec-17-2020 15:53:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP3DCZ	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-17-2020 15:53:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPLLC9	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-17-2020 15:53:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPLLC9	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-17-2020 15:53:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPLLCB	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-17-2020 15:53:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPLLCB	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Dec/02/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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I. Date of Visit

Date	Location	User	Value	Reason
Dec-09-2020 00:42:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Dec-08-2020 10:42:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	updated illness form
Dec-08-2020 05:40:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	DM: Kindly review and complete 'Illness Details form' at this visit. Thank you.
Dec-04-2020 16:17:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-03-2020 05:30:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Dec-02-2020 15:42:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Dec-02-2020 15:41:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Dec/02/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Dec-02-2020 15:41:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Dec-02-2020 15:41:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/2/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Dec-02-2020 15:41:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/02/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date of Assessment:

Date	Location	User	Value	Reason
Dec-02-2020 15:42:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/2/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Dec-02-2020 15:42:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/29/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Feb-23-2021 03:09:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed per data updated by site.
Feb-22-2021 13:57:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-22-2021 13:57:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved: Dec/7/2020	New Information
Feb-15-2021 00:59:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM : Form is unfrozen. Please review and update the Date of Last Symptom Resolved. Else, clarify.
Feb-12-2021 11:02:53 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	please unfreeze

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/02/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1161**Site Name:** (1161) Benchmark Research - San Angelo**Subject No:** 11611016**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23

Time (US & Canada)				
Feb-12-2021 05:22:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	60 days have passed since the Date of First Symptom Started and Ongoing is YES. Please confirm if symptoms are truly ongoing. Else, please enter Date of Last Symptom Resolved.
Dec-02-2020 15:42:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Dec-02-2020 15:42:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Dec-02-2020 15:42:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Dec-02-2020 15:42:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/02/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Dec-02-2020 15:42:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present: NO	Initial Entry
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4.b Symptoms:

Date	Location	User	Value	Reason
Dec-02-2020 15:42:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Dec-02-2020 15:42:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Dec-02-2020 15:42:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: NO	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/02/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

4.c Symptoms:

Date	Location	User	Value	Reason
Dec-02-2020 15:42:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Dec-02-2020 15:42:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Dec-02-2020 15:42:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Dec-02-2020 15:42:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Dec-02-2020 15:42:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Dec-02-2020 15:42:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: NEW OR INCREASED MUSCLE PAIN	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/02/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

			Symptom NO Present:	
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4.e Symptoms:

Date	Location	User	Value	Reason
Dec-02-2020 15:42:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Dec-02-2020 15:42:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Dec-02-2020 15:42:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms NEW LOSS OF TASTE OR SMELL Symptom Present: YES	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Dec-02-2020 15:42:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Dec-02-2020 15:42:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.g

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090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/02/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Date	Location	User	Value	Reason
Dec-02-2020 15:42:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCREAS s: ED SORE THROAT Symptom YES Present:	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Dec-02-2020 15:42:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SORE T HROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Dec-02-2020 15:42:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.h

Date	Location	User	Value	Reason
Dec-02-2020 15:42:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHE A Symptom Present NO :	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/02/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

4.h Symptoms:

Date	Location	User	Value	Reason
Dec-02-2020 15:42:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Dec-02-2020 15:42:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Dec-02-2020 15:42:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMITING Symptom Present: NO	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Dec-02-2020 15:42:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Dec-02-2020 15:42:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-02-2020 15:42:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other: headache	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/02/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Dec-02-2020 15:42:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: headache	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-04-2020 12:07:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other: Nasal congestion	New Information
Dec-02-2020 15:42:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other: congestion	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/02/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.b Symptoms - Other Text:

Date	Location	User	Value	Reason
Dec-04-2020 14:06:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Dec-04-2020 12:07:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Dec-04-2020 12:07:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nasal congestion	New Information
Dec-02-2020 18:29:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify CONGESTION as follows...The term is incomplete. Are you reporting NASAL CONGESTION? SINUS CONGESTION? HEPATIC CONGESTION? Other? Please update the verbatim term to clarify. Thank you.
Dec-02-2020 15:42:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: congestion	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Audit Trail
on Dec/02/2020

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Date	Location	User	Value	Reason
Dec-02-2020 15:43:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Dec/02/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Dec-02-2020 15:43:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/2/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Dec-02-2020 15:43:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWABBED MATERIAL	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Dec-02-2020 15:43:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NASOPHARYNX	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Dec-02-2020 15:43:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYNDR OME CORONAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Dec-02-2020 15:43:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TES T	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Dec-02-2020 15:44:41 (UTC-06:00) Central	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Dec/02/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Time (US & Canada)				
Dec-02-2020 15:43:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Trade Name is Other, however Trade Name Other, Specify is not completed. Please update.
Dec-02-2020 15:43:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Dec-02-2020 15:43:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: POSITIVE	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Dec-02-2020 15:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NALT Unknown	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/02/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Data Origin

Date	Location	User	Value	Reason
Dec-02-2020 15:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-02-2020 15:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-04-2020 16:17:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/2/2020	New Information
Dec-04-2020 16:17:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-04-2020 16:16:47 (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.
Dec-04-2020 16:16:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	New Information
Dec-02-2020 15:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/02/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Dec-02-2020 15:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: waiting to receive self swab	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-04-2020 16:17:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: RW79132	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-04-2020 16:17:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RW79132	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/02/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Data Origin

Date	Location	User	Value	Reason
Dec-02-2020 15:46:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-02-2020 15:46:52 (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
Dec-02-2020 15:46:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Dec-02-2020 15:46:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: subject will collect self swab	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/02/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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I.a

Date	Location	User	Value	Reason
Dec-02-2020 15:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIA LIST Occurrence of Visits NO or Contacts:	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-02-2020 15:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-02-2020 15:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Dec-02-2020 15:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitio EMERGEN ner: CY ROOM Occurrence of Vis NO its or Contacts:	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
on Dec/02/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1161**Site Name:** (1161) Benchmark Research - San Angelo**Subject No:** 11611016**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23***1.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-02-2020 15:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-02-2020 15:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.c

Date	Location	User	Value	Reason
Dec-02-2020 15:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-02-2020 15:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-02-2020 15:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.d

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/02/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Dec-02-2020 15:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner URGENT : CARE Occurrence of Visit NO s or Contacts:	Initial Entry
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1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-02-2020 15:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-02-2020 15:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Dec-02-2020 15:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practiti TELEPHONE oner: CONSULTATI ON Occurrence of NO Visits or Conta cts:	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/02/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1161**Site Name:** (1161) Benchmark Research - San Angelo**Subject No:** 11611016**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-02-2020 15:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-02-2020 15:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.f

Date	Location	User	Value	Reason
Dec-02-2020 15:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTH ER Occurrence of Visits or Contacts: NO	Initial Entry

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-02-2020 15:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-02-2020 15:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/02/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Dec-02-2020 15:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry
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090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - eCRF Audit Trail History on Dec/02/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Dec-08-2020 10:41:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNES S	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Dec-14-2020 09:10:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Closed	Response satisfies query
Dec-11-2020 14:48:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Dec-11-2020 14:48:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Respiratory Illness Diagnosis:</i> covid-19 Date of Diagnosis: Dec/2/2020	Changed Information
Dec-11-2020 13:52:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Reissued:Opened	Clin: Since local laboratory SARS-CoV-2 NAAT test result was positive on 02Dec2020 please consider updating the date of diagnosis as 02Dec2020
Dec-08-2020 10:41:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History
on Dec/02/2020**Form Version:** 06-Jul-2020 21:52**Form Status:** Data Complete, Frozen, Verified**Site No:** 1161**Site Name:** (1161) Benchmark Research - San Angelo**Subject No:** 11611016**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23

Dec-08-2020 10:41:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Respiratory Illness Diagnosis:</i> covid-19 Date of Diagnosis: Dec/1/2020	Initial Entry
Dec-08-2020 10:33:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Opened	Medical monitor: Since local laboratory SARS-CoV-2 NAAT test result was positive on 02Dec2020 please consider updating the diagnosis as "COVID-19 illness"
Dec-08-2020 10:32:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Dec-08-2020 09:57:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Medical monitor: Since local and central laboratory SARS-CoV-2 NAAT result was positive on 02Dec2020 please consider updating the diagnosis as "COVID-19 illness"

3. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-08-2020 10:41:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Dec/30/2020

Form: DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date of Visit

Date	Location	User	Value	Reason
Dec-30-2020 09:21:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/30/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Dec-30-2020 09:21:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_A1	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled
Visit on Dec/30/2020**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1161**Site Name:** (1161) Benchmark Research - San Angelo**Subject No:** 11611016**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Dec-30-2020 09:21:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-30-2020 09:21:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-30-2020 15:57:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-30-2020 09:21:43 (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.
Dec-30-2020 09:21:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/30/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-30-2020 15:57:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP3DD7	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Dec/30/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.a Sample ID

Date	Location	User	Value	Reason
Dec-30-2020 15:57:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP3DD7	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-30-2020 15:57:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPLLCV	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-30-2020 15:57:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPLLCV	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-30-2020 15:57:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPLLCW	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-30-2020 15:57:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPLLCW	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/25/2021

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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I. Date of Visit

Date	Location	User	Value	Reason
Mar-05-2021 16:24:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Mar-05-2021 06:50:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: As visit is initiated in error, please consider adding form level comment "Not applicable" in all forms. Thank you.
Mar-04-2021 16:13:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level.
Mar-04-2021 16:12:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-04-2021 16:11:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/25/2021

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

				Not Done/Not Applicable at the form level.
Feb-25-2021 17:05:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/25/2021	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Mar-05-2021 16:24:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Mar-04-2021 16:13:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ERRONEOUS VISIT	Initial Entry
Mar-04-2021 16:12:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Mar-04-2021 16:11:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ERRONEOUS VISIT	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/25/2021

Form: UNPLANNED VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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I. Assessments

Date	Location	User	Value	Reason
Mar-02-2021 01:12:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Mar-01-2021 15:37:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	updated data
Mar-01-2021 15:37:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Feb-28-2021 23:41:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	DM: Kindly consider to update this form if require else mark as Not applicable by selecting form level comment. Thank you.
Feb-25-2021 17:12:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Feb-25-2021 17:12:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Feb-25-2021 17:11:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Feb-25-2021 17:10:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/25/2021

Form: UNPLANNED VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Feb-25-2021 17:06:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Feb-25-2021 17:06:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CONTACT OUTCOME	Initial Entry

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/25/2021

Form Version: 22-Apr-2020 21:04

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Contact Type:

Date	Location	User	Value	Reason
Mar-01-2021 15:36:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Feb-25-2021 17:11:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Feb-25-2021 17:09:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Mar-02-2021 01:35:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Mar-01-2021 15:36:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	updated data
Mar-01-2021 15:36:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Feb-28-2021 23:24:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	DM: Kindly consider to update this form if require else mark as Not applicable by selecting form level comment. Thank you.
Feb-25-2021 17:11:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001**Visit:** Unplanned 1 - Unscheduled Visit on Feb/25/2021**Form Version:** 22-Apr-2020 21:04**Site No:** 1161**Subject No:** 11611016**Generated By:** (b) (4)**Form:** CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1161) Benchmark Research - San Angelo**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:23

Feb-25-2021 17:11:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Feb-25-2021 17:10:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-25-2021 17:10:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Contact: Feb/25/2021 Contact Outcome: VISIT ARRANGED	Transcription Error
Feb-25-2021 17:09:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Contact Outcome' is selected as 'VISIT ARRANGED' but no 'VITAL SIGNS' and/or 'UNPLANNED ASSESSMENT OF LOCAL REACTION' form(s) is/are entered. Please review and update as appropriate.
Feb-25-2021 17:09:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Date of Contact" is missing.
Feb-25-2021 17:09:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Contact Outcome: VISIT ARRANGED	Initial Entry

3. Comments:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/25/2021

Form Version: 22-Apr-2020 21:04

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Mar-01-2021 15:36:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: Not Applicable	Initial Entry
Feb-25-2021 17:12:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry:	Transcription Error
Feb-25-2021 17:09:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: subject is confirmed pregnant	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/25/2021

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:16

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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I. Date:

Date	Location	User	Value	Reason
Mar-05-2021 11:51:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-04-2021 16:13:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	visit is erroneous, unable to remove date
Mar-04-2021 03:47:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	DM1: Unfrozen per response, kindly review and update.
Mar-03-2021 17:01:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	this was an erroneous visit. please unfreeze
Mar-02-2021 23:53:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Opened	DMW7565086; Vitals Date is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Mar-02-2021 04:02:04 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/25/2021

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:16

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

(US & Canada)				
Mar-01-2021 15:38:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	updated data
Mar-01-2021 15:37:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Not Applicable	Initial Entry
Feb-28-2021 23:42:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly consider to update this form if require else mark as Not applicable by selecting form level comment. Thank you.
Feb-25-2021 17:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry :	Initial Entry
Feb-25-2021 17:09:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Not Done	Initial Entry

2.a

Date	Location	User	Value	Reason
Mar-01-2021 15:37:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Not Done	Initial Entry

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/25/2021

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:16

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

			Temperature: Not Applicable Temperature Unit: Not Applicable Temperature Location: Not Applicable	
Feb-25-2021 17:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: Not Done Temperature: Temperature Unit: Temperature Location:	Initial Entry
Feb-25-2021 17:09:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: Not Done Temperature: Not Done Temperature Unit: Not Done Temperature Location: Not Done	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Feb-25-2021 17:09:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Mar-01-2021 15:37:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Feb-25-2021 17:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Feb/25/2021

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:16

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Feb-25-2021 17:09:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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2.a Unit:

Date	Location	User	Value	Reason
Mar-01-2021 15:37:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Feb-25-2021 17:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Feb-25-2021 17:09:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Mar-01-2021 15:37:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Feb-25-2021 17:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Feb-25-2021 17:09:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Dec-18-2020 10:15:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/17/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-18-2020 10:15:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-18-2020 10:15:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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Date	Location	User	Value	Reason
Mar-01-2021 14:09:38 (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: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Category:

Date	Location	User	Value	Reason
Mar-01-2021 14:09:38 (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
Mar-01-2021 14:09:38 (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
Mar-08-2021 02:18:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	term updated in SDB
Mar-04-2021 03:45:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candida te	Pending SDB update
Mar-03-2021 16:41:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	yes this was submitted with the updated term on 02MAR2021
Mar-03-2021 07:20:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	SAE RECON 1: Please confirm if a follow up SAE form was submitted to update term in Safety database
Mar-02-2021 08:59:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Mar-02-2021 08:59:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exposure during Pregnancy	Changed Information

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (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: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Mar-02-2021 04:28:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2021212671, the term in both database was recorded as 'pregnancy'. Per 3 Nov EDP guidance (study communication), term should be recorded as Exposure during pregnancy. Please confirm and update accordingly.
Mar-01-2021 14:09:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Pregnancy	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-08-2021 16:54:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query
Mar-05-2021 08:08:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Mar-05-2021 08:08:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/17/2021 UNK:UNK	Changed Information
Mar-05-2021 05:01:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	As per V12 CRF CG 8.50.2.5, Date of onset is determined by ultrasound results or date of last menstrual period [LMP]. Per report, LMP is 17jan2021. Please revise/update accordingly. Thank you
Mar-01-2021 14:09:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/31/2021 UNK:UNK	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-04-2021 12:49:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-04-2021 09:50:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Mar-04-2021 09:50:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
Mar-04-2021 04:47:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM RQ: Thank you for response. The response for "Is the adverse event still ongoing?" is missing. Kindly review and update.
Mar-03-2021 17:23:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Mar-03-2021 17:23:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	subject is following up with her doctor on 09MAR2021 to get accurate dates for pregnancy. So, unsure if the term will stay the same, depending on gestational age.
Mar-03-2021 17:20:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For Exposure during Pregnancy End Date & Time 07/Dec/2020 UNK:UNK is before the Start Date & Time 31/Jan/2021 UNK:UNK.

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1161**Subject No:** 11611016**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Verified**Site Name:** (1161) Benchmark Research - San Angelo**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:23

Mar-03-2021 17:20:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Dec/7/2020 UNK:UNK	Changed Information
Mar-03-2021 16:42:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Mar-03-2021 16:42:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
Mar-03-2021 00:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "Is the adverse event still ongoing?" is missing. Kindly review and update.
Mar-02-2021 09:06:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Mar-01-2021 14:09:38 (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
Mar-01-2021 14:09:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?**If Yes, NOTIFY PFIZER IMMEDIATELY.****Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).**

Date	Location	User	Value	Reason
Mar-01-2021 14:09:38	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

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: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	NO	
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8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Mar-01-2021 14:09:38 (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
Mar-01-2021 14:09:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: relations	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-01-2021 14:09:38 (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
Mar-01-2021 14:09:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
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090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (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: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Mar-01-2021 14:09:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Mar-05-2021 09:35:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Per CRF completion guidelines the CRF is completed correctly
Mar-04-2021 09:50:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Opened	For AE Exposure during Pregnancy: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Mar-03-2021 17:23:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Mar-03-2021 16:42:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	For AE Exposure during Pregnancy: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Mar-03-2021 07:17:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-02-2021 09:06:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1161**Subject No:** 11611016**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Verified**Site Name:** (1161) Benchmark Research - San Angelo**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:23

Mar-02-2021 08:59:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE Exposure during Pregnancy: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Mar-02-2021 08:59:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Mar-02-2021 08:59:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNKNOWN	Changed Information
Mar-02-2021 04:31:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2021212671, the outcome in AE CRF was reported as NOT RECOVERED/NOT RESOLVED. Per 3 Nov EDP guidance , outcome should be recorded as UNKNOWN. Please confirm and update accordingly.
Mar-01-2021 14:09:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Mar-01-2021 14:09:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-22-2021 17:06:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/22/2021	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001**Visit:** Potential ReVax Initial Contact -
Unscheduled**Form Version:** 10-Dec-2020 02:25**Site No:** 1161**Subject No:** 11611016**Generated By:** (b) (4)**Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1161) Benchmark Research - San Angelo**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:23[Back to Form](#)**I. Select appropriate response - Is participant willing to return for Vaccination 3?**

Date	Location	User	Value	Reason
Mar-02-2021 10:27:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-01-2021 15:35:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Mar-01-2021 15:35:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return f or Vaccination 3 Participant is: eligible per other protocol al lowance(s) and confirmed to have received only placebo at Vaccination 1/2	Transcription Error
Feb-28-2021 20:57:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Please confirm if "eligible per other protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2" is more applicable
Feb-23-2021 11:09:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-23-2021 00:08:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

				complete this date.
Feb-22-2021 17:07:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-22-2021 17:07:05 (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 per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1161

Subject No: 11611016

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1161) Benchmark Research - San Angelo

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-23-2021 11:09:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/22/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-23-2021 11:09:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Subject Status

Date	Location	User	Value	Reason
Mar-02-2021 10:27:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-01-2021 15:30:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	pregnancy added
Feb-25-2021 14:16:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Please enter Pregnancy under AE logs in EDC
Dec-18-2020 10:15:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-02-2020 15:33:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-02-2020 15:14:20 (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
Dec-18-2020 10:15:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Dec/17/2020	Initial Entry
Aug-02-2020 15:33:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/1/2020	Initial Entry
Aug-02-2020 15:14:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/1/2020	Initial Entry

090177e196ae3d53\Final\Final On: 01-Apr-2021 04:31 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1161

Site Name: (1161) Benchmark Research - San Angelo

Subject No: 11611016

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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I. Casebook Signature

Date	Location	User	Value	Reason
Sep-11-2020 11:02:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Darrell Herrington (b) (4)	Data Entry: Click Here to Enable	Initial Entry